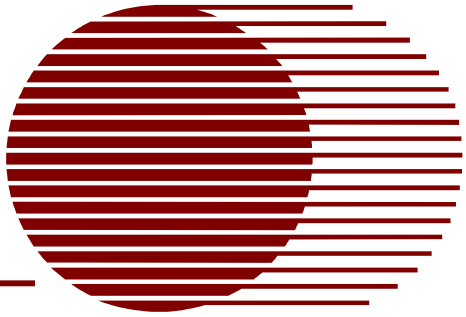
A Report to the
Joint Legislative Sunset Review Committee

Board of Pharmacy
Sunset Review
Report
2002



National Awards Won by the Board of Pharmacy

1997 Fred T. Mahaffey Board of the Year Award
from the National Association of Boards of Pharmacy for demonstrating outstanding leadership in protecting the public and specifically, for the board's public education and consumer outreach program.

1999 Paul G. Rogers Medication Communicators Award
from the National Council for Patient Information and Education for the board's consumer awareness and outreach program.

2002 CLEAR Program Award
from the Council on Licensure, Enforcement and Regulation for the board's innovation in developing a mandatory quality assurance program for pharmacies for the evaluation of prescription errors and enhancement of consumer protection.

For additional copies of this report, please contact:
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814
(916) 445-5014
www.pharmacy.ca.gov

California State Board of Pharmacy

Members

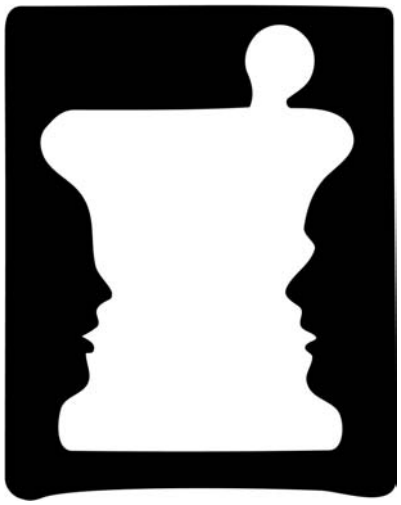
John D. Jones, R.Ph., President
Donald W. Gubbins, Jr., Pharm.D., Vice President
David J. Fong, Pharm. D.
Stanley Goldenberg, R.Ph.
Clarence Hiura, Pharm. D.
Steve Litsey, Pharm.D.
William Powers
John Tilley, R.Ph.
Caleb Zia
Andrea Zinder

Vision

Healthy Californians through quality pharmacists' care.

Mission

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacists' care through education, communication, licensing, regulation, and enforcement.



BE AWARE & TAKE CARE
Talk to your Pharmacist!

September 1, 2002

Message to the Members of the Joint Legislative Sunset Review Committee:

The report is divided into four sections:

- ***Overview:*** containing board recommendations for future consumer protection activities, the board's significant accomplishments over the last four years, pharmacy legislation enacted and regulations promulgated.

- ***Board Committees:*** describing the board's five standing policy committees and their major activities over the last four years, and schedules of meetings.

- ***Part 1:*** responding to questions asked by the Joint Legislative Sunset Review Committee in Part 1 of their survey.

- ***Part 2:*** responding to questions asked by the Joint Legislative Sunset Review Committee in Part 2 of their survey

For the committee's ease in reviewing this report, material presented in Parts 1 and 2 follows the same order as the committee's survey questions.

Table of Contents

Overview

Board Committees

PART 1 – Background Information and Overview of the Current Regulatory Program

(This section contains information requested by the Joint Legislative Sunset Review Committee's Sunset Review Survey, Part 1)

PART 1 (continued)

PART 2 – Board's Response to Issues Identified and Former Recommendations Made by the Joint Legislative Sunset Review Committee

(This section contains information requested by the Joint Legislative Sunset Review Committee's Sunset Review Survey, Part 2)

Tables and Figures

Overview

Introduction ·

Proposals to Strengthen Public Protection Efforts · and Improve Operational Efficiencies

Significant Accomplishments and Major Milestones ·

Legislation and Regulation Changes · to California Pharmacy Law

Blank Intentionally

OVERVIEW

INTRODUCTION

The Board of Pharmacy (or "board") is a consumer protection agency, charged with protecting the state's consumers with respect to prescription drugs and devices. The board has 12 major regulatory programs that regulate both the individuals and firms that ship, store, and dispense prescription drugs and devices to the state's health care providers and patients. This is an enormously large area of the state's economy. In 1999, retail spending in California for prescription drugs was $9.3 billion alone.[1]

In the next two years, use of prescription drugs is expected to skyrocket. Nationally, estimates are that between 1990 and 1999 the number of prescriptions dispensed in non-hospital settings increased by 44 percent, from 1.9 billion to 2.8 billion. However by 2004, the number of prescriptions dispensed is expected to exceed 4 billion. This growth in the number of prescriptions dispensed directly impacts the board's workload in terms of the number of applicants, licensees, complaints, and public inquiries. Moreover, this growth in prescription volume has and will result in a huge shortage of pharmacists, directly impacting the profession, the board as a regulator and the patients and health care providers who need prescription drugs readily available.

A December 2000 Report to Congress – *The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists* reported a national average of 71 pharmacists per 100,000 people. However, California has an average of only 59 pharmacists per 100,000 people. Moreover, a 44 percent growth occurred in prescription volume between 1992 and 1998. This growth outpaced the increase in both the general population (7 percent) and the number of active pharmacists (12 percent).

Over the past several decades, health care has undergone a continuous period of revolutionary change. Likewise, the practice of pharmacy has rapidly evolved in new directions as well. The result is intense pressure upon the board to change, to anticipate and certainly react to emerging issues, increasingly to seek legislative and regulation changes that will assure patient care, confidence and availability of prescription medication in the prescription drug delivery system. The board has also met this challenge in a number of additional ways, to develop new methods for licensing and enforcing our laws, and in increasing the knowledge of patients about their medications and the role of the board.

Since the board's first sunset review six years ago, the board has evolved into a stronger

[1] According to *Prescription Drug Use and Expenditures in California, Key Trends and Drivers*, California HealthCare Foundation, April 2001.

agency and has been increasingly successful in fulfilling its mandate of consumer protection. For example, since 1996 (among its many accomplishments):

- The board's public education and outreach efforts have produced two national awards in the last six years.
- The board sponsored and implemented groundbreaking legislation to reduce medication errors, for which the board has won another national award and which at least one other state has used as its model to address prescription errors.
- The board adopted regulations to enforce the Confidentiality of Medical Information Act.
- The board has significantly reduced investigation and case closure times.
- The board sponsored and is implementing legislation to dramatically increase the licensing requirements and standards of practice for pharmacies compounding sterile drugs.
- The board reorganized and modernized its licensing act and regulations.

This report will describe the board's activities over the past six years and its future plans.

Pharmacy Trends

Pharmacy is increasingly caught between twin (and frequently contradictory) trends. The first is the dramatic increase in the volume of prescriptions. The rapid increase in the number of prescriptions has focused much discussion on how the system will respond to this increase in prescription volume. At the same time, pharmacists are increasingly valued for their clinical skill and expertise with drugs. The employment of pharmacists in hospitals and other care settings to advise physicians on drug therapy and work directly with patients to optimize drug therapy is on the rise. This leaves pharmacy with pressure from two opposite directions with growing demand for both dispensing activities and for their clinical expertise. These twin pressures have driven (both in pharmacy and in health care generally) interest in automation, Internet technology, and electronic prescribing as means to address workforce shortages and increasing the quality and efficiency of pharmacy services.

In addition to accommodating increasing demand for dispensing and clinical services, pharmacy faces dramatic changes from other directions. The recent and rapid growth of prescription drug benefit coverage introduces the complications of third party reimbursement and formularies, a surge in the number of new prescription medications, growing use of "alternative medications," direct-to-consumer advertisements for prescription drugs creating strong consumer demand for specific drugs, and growth in the number of health care professionals who can prescribe. Meanwhile, cost containment and technological innovations in the broader health care system continues to move complex patient care from hospitals to office settings and into in-home care. As a result, patients and their caregivers must learn more and more about their health care

and medication treatment plans. Pharmacists play a key role in providing patients and their caregivers with information about their drug therapy.

These same trends have also placed a growing amount of confidential patient information in the hands of pharmacists and other health care practitioners. Consumers have become sensitized to the use and sharing of such information, and patient privacy issues regarding the sharing of prescription information will grow. The unauthorized sharing of confidential patient information with other entities or careless handling of patient information undermines the public's trust in pharmacy and health care in general, and violates California law. The board will increasingly become involved in this area because of the growing public concern and the presence of extensive patient information in pharmacy data systems.

Pharmacists' Care

The board promotes pharmacists' care as a model of practice. Pharmacists' care is a comprehensive approach stressing the importance of pharmacists consulting with their patients, conducting patient profile reviews, managing drug dispensing and distribution, and collaborating with other health care providers. The pharmacists' care model emphasizes increasing patients' knowledge about their medications and stresses the importance of patients maintaining their drug regimens in close consultation with pharmacists.

Pharmacy practice continues to evolve from the dispensing of prescription drugs and devices to the provision of pharmacists' care to patients. Technology permits and encourages this shift in emphasis by facilitating the pharmacist's role in drug utilization and consultation. And in the near future, technology will play an even more critical role in pharmacy as the demand for pharmacists' increases to meet the increasing demand for prescription drugs of an aging population, yet the supply of pharmacists is expected to grow at a substantially slower pace.

The role of the pharmacist as a member of the health care team must be relied upon to a greater extent than current practices dictate. This requires continual update of pharmacy law to permit the pharmacist to manage the drug distribution process, focus on pharmacists' care and provide ever-greater patient services and education.

Patient Health Issues

Nearly 50 percent of the billions of prescriptions dispensed annually are not taken appropriately, leading to increased health care costs and substandard therapy. A study published in March 2001 found that drug-related illnesses cost the healthcare system over $177 billion per year in ambulatory settings, more than double the estimated amount of such costs in 1995. And a projection of 4 billion prescriptions to be dispensed in 2004 creates an even greater incentive to improving patients' understanding of and compliance with drug regimens.

Finding effective methods to improve patient medication compliance to a prescribed drug regimen offers health care providers with one of the most dramatic and constructive

ways to slow the increase in health care costs while improving patient outcomes. Additionally increasing use of technology in the pharmacy is needed so that the pharmacist has the time necessary to perform pharmacists' care.

Prescription errors endanger public safety and confidence in the health delivery system. According to a 1999 *Institute of Medicine Report*, there are 7,000 deaths nationwide due to prescription errors. While perhaps not all prescription errors can be wholly eliminated, there is no acceptable error rate. Prescription errors are the most common consumer complaint received by the board.

The board has responded to the focus on quality by sponsoring Senate Bill 1339 (Figueroa, Chapter 177, Statutes of 2000) that requires pharmacies to implement quality assurance programs designed to reduced medication errors. Pharmacies must now engage in documented continuous quality improvement efforts, which will reduce the frequency of medication errors and provide a model for pharmacies to improve all aspects of their operations.

The Board

The board has a highly complex regulatory structure with almost 76,000 licensees in 12 regulatory programs, and staff resources are not sufficient to provide consumer protection at desired levels. There are 6,124 pharmacy sites and 710 clinics to be inspected. Additionally there are 30,962 registered pharmacists, 3,674 interns and another 31,235 pharmacy technicians regulated by the board. Finally, there are over 1,300 other sites registered in California by the board, many of which require periodic inspections.

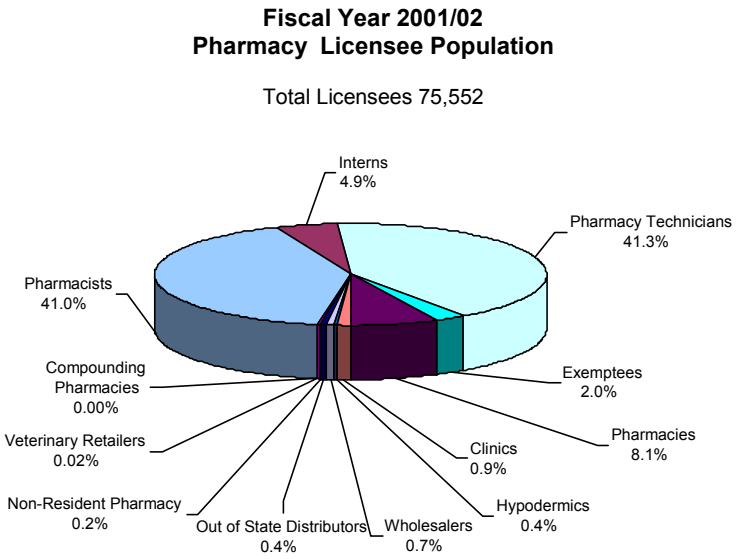


Figure A - Pharmacy Licensee Population

Consumers have the right to expect that those to whom the responsibility of prescribing and dispensing drugs is authorized, are knowledgeable and are not influenced by profit or affected by impairment. Enforcement, including the diversion of prescription drugs for illicit purposes, remains the board's major public protection priority and commands the majority of board resources. However, specialized programs used to target pharmacies suspected of illicit activities are not optimally operating due to limited staff resources.

Because of the dynamism in pharmacy, the board must continue to change the way it provides consumer protection and its services to licensees. It also needs to develop alternative, less costly methods for securing compliance with pharmacy law. To do this, the board needs highly trained and dedicated staff that is adept at responding to change based on the direction of decisive and visionary board members acting in the public interest.

Blank Intentionally

PROPOSALS TO STRENGTHEN PUBLIC PROTECTION EFFORTS AND IMPROVE OPERATIONAL EFFICIENCIES TO BETTER SERVE CONSUMERS AND LICENSEES

The Board of Pharmacy has a number of strategic activities it will pursue over the next few years to advance consumer protection, pharmacists' care and to attain the board's mission and vision. These activities are detailed in the board's strategic plan. Among these activities are certain key initiatives that are highlighted below:

Communication and Public Education

- Restore two associate governmental program analyst positions lost because of the state's budget deficit in 2002/03. These positions are necessary for program support and to resume the board's award winning public outreach program, quarterly publication of the board's newsletter, annual publication of Health Notes, and interactive website.

Licensing

- Use the national examination [North American Pharmacist Licensure Examination (NAPLEX)] to remove an unnecessary administrative barrier to the practice of pharmacy in California while maintaining a high standard of competence that consumers expect from their pharmacists.
- Address pharmacy manpower issues to ensure patient access to pharmacists' care and prescription services. This will include the expansion of the pharmacist's control over ancillary personnel and review and modification of the registration program for pharmacy technicians including qualifications, national certification and expanded duties.
- Authorize the use of technology that allows for the accurate dispensing of medication with quality assurance review and oversight by the pharmacist, biometric authentication, and e-signature.
- Explore the feasibility of specialized pharmacy licenses and practice standards to address evolving trends in areas such as sterile compounding, long-term care, correctional facilities, ambulatory care settings that provide inpatient services, nuclear pharmacy, correctional facilities, and pharmacies operated remotely by a pharmacist offsite.
- Expand automation capabilities to provide on-line, real time application status information, on-line renewal of licenses, and application submissions and credit card payments of fees.

Enforcement

- Create and fund a high-level chief of enforcement position to oversee and manage the board's complex and diverse enforcement program and four supervising inspectors.
- Mandate periodic inspections of all pharmacies and other board-licensed sites with appropriate staffing levels to meet this mandate.
- Eliminate the triplicate prescription requirement for Schedule II controlled substances and expand the current electronic tracking of Schedule II controlled substances (CURES) to Schedules III-V to prevent drug diversion and improve patient care through better pain management.
- Implement the 800 number on the board's revised "Notice to Consumers" that must be posted in all pharmacies and obtain staffing necessary to respond to consumer inquiries and complaints timely.
- Obtain the requested resources to proactively investigate and prosecute pharmacies for violating Internet provisions by dispensing prescription drugs to patients who did not receive a good faith medical examination or lack legitimate prescriptions.

Organizational Development

- Reinstate four positions lost because of the state's budget deficit in 2002/03. These positions are vital to the board's operations and service to the public and licensees (the two public education positions, and two consumer assistance technicians).
- Receive repayment of $6 million loan (or portion thereof) from the General Fund by July 1, 2003, or a fee increase will be necessary to continue operations as will an increase in the statutory maximum fees. The board will need to hold a regulation hearing to increase fees at its January 2003 board meeting in order to implement higher fees by July 1, 2003. Without the repayment of the loan or fee increase, the board has a $2.4 million gap between its revenue and expenditures in 2003/04.
- Obtain a budget realignment of $530,000 for 2002/03 and $618,000 ongoing. This realignment is necessary to provide funding to budget areas that have been under-funded in prior years, but which were partially funded from salary savings from unfilled inspector positions or redirected from other budget areas. Specifically:

Printing	$60,000 for 2002/03, $158,000 ongoing
Postage	$75,000 for 2002/03 and ongoing
AG's Office	$262,000 for 2002/03 and ongoing
Personnel	$132,700 for temporary help, proctors and overtime 2002/03 and ongoing

- Obtain use of a new computer system that provides for the tracking of licensing, enforcement, application and cashiering data with the ability to image documents, to replace current system that has been in place in the Department of Consumer Affairs for at least 18 years.

Significant Accomplishments and Major Milestones 1997 to Present

1997

- Sunset recommendations released as SB 827, Chapter 759 add one public member to the board's composition (enacted), remove the mandate that board inspectors be pharmacists (not enacted), authorize the use of in-house attorneys to prosecute disciplinary cases (not enacted), and continue board operations with a sunset date of 2004.

- Board provides $1 million to fund the implementation of AB 3042, Takasugi, Statutes of 1996 a pilot study to electronically monitor Schedule II controlled substances in California (called CURES).

- Board-sponsored legislation (SB 1349, Senate Business and Professions Committee) updates pharmacy law to current practice; more than 75 substantive changes are made to California pharmacy law in this major initiative.

- Two-year limited funding for the board's public education and consumer outreach program begins.

- Veterinary Food-Animal Retailers licensure program is implemented requiring specialized site licenses and licenses to specially qualified individuals who pass a board-developed exam.

- Advocate board positions and amendments into 16 legislative bills that affect the practice of pharmacy.

- Nine regulation proposals are considered by the board and six regulation changes are adopted.

- An emergency regulation is adopted to permit students enrolled in a pharmacy technician-training program to obtain the required practical experience in a pharmacy.

- Department of Consumer Affairs conducts an Internal Affairs investigation of the Board of Pharmacy based on anonymous complaints alleging mismanagement and criminal activity. (*See 1998 Significant Accomplishments for the investigation results.)*

- The California State Auditor completes its financial audit of the board and issues three findings pertaining primarily to the Department of Consumer Affairs; the board is found to be in general compliance.

1997 continued

- Board convenes roundtable discussion on independent prescribing authority for pharmacists.
- Board sponsors a public presentation on pharmacy benefit management and its impact on patient care.
- Major revision of the board's strategic plan reorganizes operations into five policy committees corresponding to the board's five goal areas: Enforcement, Licensing, Communication and Public Education, Legislation and Regulation, and Organizational Development.
- Federal legislation requires a memorandum of understanding (MOU) be developed between the federal Food and Drug Administration (FDA) and each state in order for a pharmacy to distribute compounded medications to patients in other states, and requires the Board of Pharmacy to investigate complaints regarding the distribution of compounded medications.
- Detail systems requirements are prepared for the new computer system of the Department of Consumer Affairs (Integrated Consumer Protection System or ICPS). The Department later abandons the system.

1998

- "Fred T. Mahaffey Board of the Year" award bestowed upon the board by the National Association of Boards of Pharmacy for board operations and specifically the public education and consumer outreach program.
- Emergency regulations are adopted to require pharmacies to submit data electronically to implement CURES. Pharmacies submitting data to CURES within the first three months receives a one-time license renewal rebate of $75 per pharmacy.
- Two contracts are awarded to automate the tracking system to monitor the prescribing and dispensing of Schedule II controlled substances (CURES) in California, at a cost of $350,000 per year.
- Board co-sponsors with the U.S. Department of Health and Human Resources and the Health and Welfare Agency, a Summit of Healthcare Payers and Providers to demonstrate the cost effectiveness of pharmacists' participation in improving patient medication compliance. The board later produces a journal on how to sponsor such a summit. Board updates its strategic plan.

1998 continued

- Board enlists the support of State and Consumer Affairs Agency and the Department of Personnel Administration to resolve the salary inequity for board inspectors and to obtain an administrative remedy to the problem.
- Monitors and takes position on approximately 18 legislative bills that affect the practice of pharmacy, pharmacists' care of patients, or board operations.
- SB 2239 (Business and Professions Code) sponsored by the board, contains six provisions to amend pharmacy law and the Health and Safety Code.
- Board approves UCSF research study of technicians checking technicians at hospital in-patient pharmacies of Long Beach Memorial Center and Cedars Sinai Medical Center.
- The board develops an action plan to strengthen communication among the board and its staff, integrates the action plan into the board's strategic plan, and improves cohesive staff development and team training. Department of Consumer Affairs releases its Internal Affairs investigation findings on the Board of Pharmacy management and concludes there is no evidence to support the 1997 allegations.
- Transition Monitoring Team is created of nine elected to facilitate communication throughout the board during the board's transition to a new organizational structure.
- All board staff completes a yearlong training program titled "Bullet Proof Manager" to provide staff with the skills necessary to handle change and to better manage themselves on the job.
- The Enforcement Committee holds quarterly facilitated meetings with board inspectors to implement the board's strategic plan, and address issues of organizational change, deficient pharmacist salaries, vacancies, and reorganize work assignments statewide.
- Inspectors design and board implements a statewide "team" model to conduct investigations and inspections.
- Six regulation proposals are considered and two regulation changes are adopted.

1999

- Board is awarded the inaugural Paul G. Rogers Medication Communicators Award from the National Council on Patient Information and Education Council for the board's consumer awareness and outreach program.
- Board implements a self-assessment regulation to require all pharmacies to perform a self-inspection of its facilities every time a pharmacy opens, when there is a change in the pharmacist-in-charge, and at least every two years.
- Board sponsors SB 1308 (Senate Business and Professions Committee) to add or amend 13 provisions of pharmacy law, including the extension of the CURES' sunset provision to 2003. One provision again links the inspector salary to the salary of pharmacists who work in the University of California system. Due to opposition from the Department of Personnel Administration, this provision is amended out.
- Through long-term and persistent board activities, inspectors receive a one-time 14 percent salary increase through the collective bargaining process with a total increase of 22 percent over an 18-month period. (A higher salary was necessary to recruit quality pharmacists for its inspector program; at one point this year, the board had 10 inspector positions vacant out of 19.)
- Fees are reduced to the levels that were in effect before July 1995, because of the return of $5.4 million transferred to the state's General Fund in 1991/92.
- California becomes the first state to adopt regulations to authorize the refill of prescriptions from one centralized pharmacy location to be dispensed to patients from other pharmacies creating automation and processing efficiencies.
- Advocates board positions and amendments into 22 legislative bills that affect the practice of pharmacy, pharmacists' care of patients or board operations.
- Fourteen regulation proposals are considered and four regulation changes adopted.
- Task force with other regulatory and law enforcement agencies formed to review CURES data to identify excessive levels of prescribing and dispensing and to coordinate resources to target prescribers and pharmacies for investigation.
- Triplicate prescription exemption for terminally ill patients, a major change in the prescribing requirements for Schedule II drugs, becomes law and board begins major education of profession about the change.

1999 continued

- Emergency regulations are adopted to permit the temporary absence of pharmacists from a pharmacy for breaks and lunch periods under new provisions of the Labor Code and orders of the Industrial Welfare Commission.
- Regulations are proposed to require pharmacies to implement a quality assurance program to prevent the recurrence of prescription errors, but at the request of the board's stakeholders, the board tables the regulation to instead seek legislative authority for a discovery exemption for the quality assurance program.
- An independent assessment of the effectiveness of the board's consumer education and outreach efforts is conducted which provides a baseline justification to continue the funding for the board's consumer education program.
- Two monographs are published for pharmacists (Health Notes), one on women's health and the other on pharmacist management of anticoagulant therapy.
- Contracts to fund CURES through December 2001 are extended; all funding comes from the original $1 million appropriation in 1996.
- New federal law mandates the board to report disciplined pharmacists and pharmacies to a Health Care Professional Data Bank.
- Board's software is upgraded, a new telephone system installed, and a business continuity plan is developed to ensure Y2K compliance.
- Board convenes a Medication Information Technology Task Force to review the legality of patient compliance programs and address issues of patient confidentiality.
- Findings of an independent audit of the board's fees are released. Many fees are close to the board's actual cost of providing the service; the fees for pharmacy technicians, interns and the regrade of pharmacist examination are substantially lower than the actual cost of the services.
- One board inspector becomes first non-peace officer in the nation to be certified as a drug recognition expert.
- Two public forums are held on the pharmacy manpower shortage to assess the magnitude of the problem and seek solutions.
- Board updates its strategic plan.

2000

- Board sponsors SB 1339 (Figueroa) to require pharmacies to implement quality assurance programs to prevent prescription errors from recurring and exempts from discovery the data from the quality assurance program.

- Board sponsors AB 2018 (Thomson, Runner and Migden) to make CURES (the electronic tracking of Schedule II controlled substances) permanent and eliminate the triplicate prescription requirement for Schedule II controlled substances. Bill is later substantially amended due to opposition wanting to maintain triplicate system indefinitely.

- Board implements SB 393 (Speier) that requires pharmacies that dispense prescription medications to Medicare patients be sold the medications at the Medi-Cal price if the patient pays cash for the prescription medication. Board also develops a consumer brochure that is widely distributed and placed on the Governor's website.

- A specialized mediation team of non-inspector analysts is established to focus on the resolution of consumer complaints. Inspectors also trained on the mediation process. Board routine inspections are suspended and inspectors directed solely to resolve consumer complaints and investigations over one year old because of a 42 percent inspector vacancy rate and a backlog of cases.

- Board sponsors SB 1554 (Business and Professions Committee) to among other provisions, authorize the restocking of ambulances with prescription drugs used to treat patients.

- Board sponsors conference on CURES to consider the direction of California's policy regarding the electronic monitoring of Schedule II controlled substances. Presenters and participants include federal and state law enforcement agencies, regulatory agencies, the Legislature, professional health associations, consumers, nationally recognized pain management specialists, pain management advocates and consumers.

- Board supports SB 1828 (Speier) that authorizes the board to assess a $25,000 fine per violation against pharmacies that dispense Internet prescriptions without a good faith medical examination. A legislative budget change proposal to enable the board to aggressively implement these provisions is denied.

- Board monitors and takes position on 13 legislative bills that affect the practice of pharmacy, pharmacists' care of patients or board operations.

- Board considers 10 regulation proposals and adopts five regulation changes.

2000 continued

- Board releases an independent statewide public survey to establish a benchmark for measuring the effectiveness of the board's consumer education and outreach program. Nearly 75 percent surveyed have never heard of the Board of Pharmacy, and yet after being advised about the board, 92 percent believe that such an entity was essential for public protection.
- Job analysis for the California pharmacist licensure examination is completed and a new examination content outline is developed for exam that is used beginning with the June 2001 examination.
- Board publishes a fourth monograph journal (Health Notes) on the care of children and adults with developmental disabilities.
- New board interactive website is activated that includes substantially more information on the board's licensing programs and complaint process, application forms, agendas, and minutes for all board and committee meetings, positions on pending legislation and regulations, and publications such as consumer brochures.
- Comprehensive articles on the confidentiality of pharmacy information and the sales and restrictions of ephedrine products are published in the board's newsletter.
- Policy and procedures manual for board members is developed.
- Board updates its strategic plan.
- Board's Sacramento office expands to meet the growing needs of board.

2001

- Board sponsors five significant legislative proposals; all are enacted:
  - SB 293 (Figueroa and Torlakson) – requires a separate license for a pharmacy that compounds injectable sterile drugs and adherence to board standards for compounding injectable sterile drugs.
  - SB 340 (Speier) – allows a clinic eligible for participation in the federal 340B program to contract with a pharmacy to dispense 340B drugs to patients of the eligible clinic.
  - SB 724 (Business and Profession Committee) – corrects several provisions of pharmacy law for wholesalers, allows for a temporary permit for a change of ownership, and makes cash compromise for Medi-Cal violations unprofessional conduct.
  - AB 809 (Salinas) – permits the use of automated dispensing devices by licensed clinics that are controlled and operated by a pharmacist off-site.
  - AB 826 (Cohn) – permits pharmacists to perform clinical and consulting functions outside a licensed pharmacy and initiate a patient's drug therapy in all practice settings in accordance to a physician's protocol.

2001 continued

- Board adopts regulations to require every pharmacy to implement a quality assurance program to prevent prescription errors from reoccurring. California is the first state to do this.
- Convenes a 15-member task force that includes representatives from the professional associations, the four schools of pharmacy, labor organizations, and the public to seek solutions to the pharmacist shortage in California to ensure patient's access to pharmacists' care and prescription services.
- Commissions an independent audit of the North American Pharmacist Licensure Examination (NAPLEX). The audit concludes that the national examination used by all states except California is a valid measure of competencies essential for entry-level pharmacists.
- Board votes to use the NAPLEX as the California pharmacist licensure examination based on specified conditions including applicants must also take and pass a California jurisprudence examination. Legislation is needed to enact.
- Board monitors and takes position on 21 legislative bills that affect the practice of pharmacy, pharmacists' care of patients or board operations.
- Board considers seven regulation proposals and adopts four regulation changes.
- Board reinstates routine pharmacy compliance inspection program. The goal is to inspect all pharmacies every three years.
- The Bureau of State Audits releases its findings that the board does not promptly resolve complaints and may have violated compensation and record keeping requirements of the federal Fair Labor Standards Act. The report concludes that had the inspector vacancies been filled, there would not have been a backlog of consumer complaints.
- Publishes the fifth monograph journal (Health Notes) on alternative medicines.
- Transfers the medical device retailer program to the Department of Health Services in accordance AB 1496, Olberg, Chapter 837, Statutes of 2000.
- Implements FBI background checks for all board applicants and replaces the California background check of using fingerprint cards with the new automated Live Scan process.
- Board updates its strategic plan.

2002

- Implements the quality assurance regulation that requires all pharmacies to have a quality assurance program to prevent prescription errors from recurring.
- Adopts a regulation to revise the "Notice to Consumers" that is posted in all pharmacies to advise consumers on the importance of talking to the pharmacist. Redesigns the poster containing the notice to improve the graphics.
- Proposes regulations to establish standards for pharmacies that compound sterile drug products and implemented the new licensing and program for pharmacies that compound injectable sterile drug products.
- Adopts a regulation that permits the board to issue a fine up to $25,000 for each violation of dispensing prescription drug via an Internet prescription and without a good faith medical examination by a prescriber.
- Adopts a regulation that permits the board to issue a fine up to $25,000 for each violation of the Confidentiality of Medical Information Privacy Act.
- Assesses $88.7 million in fines against a pharmacy and two pharmacists for allegedly filling Internet prescriptions without a "good faith prior medical examination."
- Implements regulations to expand the board's authority to cite and fine for any violation of pharmacy law. A two-member committee issues the citations and fines.
- Publishes its sixth monograph (Health Notes) on quality assurance programs and contracts to develop a seventh monograph on geriatrics.
- Begins development of an emergency contraception brochure for pharmacists to provide to patients receiving emergency contraception.
- Board substantially revises its strategic plan, which includes new vision and mission statements.
- Submits Sunset Review Report – September 1, 2002

Blank Intentionally

Legislation and Regulation Changes to California Pharmacy Law

1997 to Present

1997

Business and Professions Code, Section 4001(a)
The authority for the Governor to appoint a new public board member is added.

Business and Professions Code, Section 4004
A board member is authorized to teach an approved continuing education course.

Business and Professions Code, Section 4008(a)
The board is authorized to use non-pharmacist inspectors, except when the inspector's responsibilities primarily involve investigation or inspection of a pharmacy. The board inspector is also authorized to inspect a physician's office or a clinic to the extent necessary to determine compliance with recordkeeping requirements.

Business and Professions Code, Section 4009
The authority of board members to participate in inspections or investigations of licensed premises is repealed.

Business and Professions Code, Section 4016
The board revises the definition of "administer."

Business and Professions Code, Section 4021
The term "controlled substance" is simplified.

Business and Professions Code, Section 4022
The board includes as a dangerous drug any drug, which is unsafe for "self-use."

Business and Professions Code, Section 4023
The definition of "device" is expanded.

Business and Professions Code, Section 4024 (and 4174)
A pharmacy may fill the furnishing orders of nurse practitioners, nurse midwives, physician assistants, and pharmacists acting within the scope of their practice.

Business and Professions Code, Section 4025.1
The definition of "nonprescription" drug is added.

Business and Professions Code, Section 4034
A medical device retailer is no longer required to file plans with the application.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T.

Business and Professions Code, Section 4037
The definition of pharmacy is amended by eliminating the reference to structured plans.

Business and Professions Code, Section 4043
Wholesalers are prohibited from storing their drugs or devices with any person or at any premises not licensed by the board.

Business and Professions Code, Section 4051
Pharmacists are authorized to initiate a prescription or to provide clinical advice, information or patient consultation from outside a pharmacy if the information is provided to another health care professional or to a patient of or resident in a licensed acute care hospital, a health care facility, home health agency or hospital. In addition, the pharmacist has access to prescription, patient profiles or other relevant medical information and the above information is secured from unauthorized access.

Business and Professions Code, Section 4052(a)(7)
The function of a pharmacist is updated to include providing consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

Business and Professions Code, Section 4053(c)
An exemptee certificate for a manufacturer, wholesaler, medical device retailer or veterinary food-animal retailer is valid only at the location issued and that the licensee and exemptee must notify the board in writing within 30 days when the exemptee is no longer employed at that location.

Business and Professions Code, Sections 4054 and 4059(c) and (d)
Code references are changed from "hemodialysis" to "dialysis."

Business and Professions Code, Section 4058
Pharmacists are no longer required to display their licenses in a pharmacy.

Business and Professions Code, Section 4059.5
Drugs must be delivered to licensed premises, only a licensee of the board can order prescription drugs and prescription devices and only a pharmacist-in-charge, or another pharmacist designated by the pharmacist-in-charge, is authorized to handled the prescription drugs or prescription devices.

Business and Professions Code, Section 4062
The law is updated as to what constitutes an emergency by referencing federal, state or local emergency as to when a pharmacist can provide drugs.

Business and Professions Code, Section 4064
The situations are expanded as to when a pharmacist may refill a prescription when the prescriber is unavailable.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T.

Business and Professions Code, Section 4070
An electronic data prescription must be printed out by the pharmacy (or reduced to writing); however, a faxed prescription need not be.

Business and Professions Code, Section 4071 and 4072
A pharmacy must make a reasonable effort to confirm that a person who transmits a prescription as the agent of the prescriber is authorized to do so.

Business and Professions Code, Section 4074
The requirements for auxiliary labels are simplified.

Business and Professions Code, Section 4078
The use of false or misleading labels on prescriptions is specifically barred.

Business and Professions Code, Section 4080
Board inspectors are authorized to inspect anyone that maintains dangerous drugs and devices.

Business and Professions Code, Section 4081(a)
Licensees are required to maintain all acquisition records.

Business and Professions Code, Section 4082
The board's authority to demand the names and capacity of persons employed by any licensed entity of the Board of Pharmacy is expanded.

Business and Professions Code, Section 4100
All board licensees are required to notify the board of any address change within 30 days of moving.

Business and Professions Code, Section 4101(a)
A pharmacist who is in charge of any board-licensed entity must notify the board of his or her termination of employment.

Business and Professions Code, Section 4101(b)
An exemptee is required to notify the board within 30 days of termination from employment.

Business and Professions Code, Section 4102
Pharmacists are authorized to perform simple blood withdrawal procedures for patients.

Business and Professions Code, Section 4103
Pharmacists are allowed to take a person's blood pressure without special training.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T.

Business and Professions Code, Section 4104
A pharmacy is required to have procedures in place to protect the public where the pharmacy is aware of a licensed employee with a mental, physical or substance abuse problem which affects his or her ability to do his or her work safely, or where the pharmacy is aware that a licensed employee is stealing, diverting, or self-using drugs from the pharmacy. The board may establish requirements for reporting to the board the conduct or incidents regarding such employees.

Business and Professions Code, Section 4105
Pharmacies are required to keep records on the licensed premises; however, the board may grant a waiver to store the records off-site in a secured area.

Business and Professions Code, Section 4110(a)
The board is authorized to determine under what circumstances a license may be transferred and authorizes the board to grant a temporary license in a case of an ownership change.

Business and Professions Code, Section 4111(e)
The board can require or ask for information it deems "reasonable" regarding an application for a pharmacy license.

Business and Professions Code, Section 4115(a)
A pharmacy technician can only perform authorized activities while assisting a pharmacist and the pharmacist must be on the premises where the technician is working.

Business and Professions Code, Section 4117
The pharmacy technician is added to the list of those who can be in a pharmacy.

Business and Professions Code, Section 4118
The board is authorized to waive any requirements for licensure.

Business and Professions Code, Section 4119.5
The law is clarified as to when a pharmacy has the authority to transfer drugs to another pharmacy, the authority for repackaging and to furnish drugs for prescriber office use.

Business and Professions Code, Section 4122
A pharmacy can provide a written notice of the availability of price information to be included with a prescription as an alternative to posting a sign in the pharmacy.

Business and Professions Code, Section 4130(c)
The law is clarified that the issuance of a temporary permit for a medical device retailer is discretionary.

Business and Professions Code, Section 4132
A medical device retailer is required to make sure that customers know consultation is available.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T.

Business and Professions Code, Section 4133
A pharmacist can be in charge of a medical device retailer.

Business and Professions Code, Sections 4136 and 4136.5
Category of nonresident medical device retailer is created that must be registered with the board.

Business and Professions Code, Section 4160(c)
A separate wholesale license is required for each place of business operated by a wholesaler.

Business and Professions Code, Section 4165
Out-of-state manufacturers are required to provide records of transactions with California customers and be subject to citation and fine for failure to do so.

Business and Professions Code, Section 4166
A wholesaler or other distributor is responsible for the security and integrity of any delivery of any dangerous drugs and dangerous devices through any carrier that it selects, up to the point of receipt by the licensed customer.

Business and Professions Code, Section 4167
A wholesaler cannot order or obtain more dangerous drugs or dangerous devices that it can store securely on the licensed premises.

Business and Professions Code, Section 4170
Dentists are added to the prescriber dispensing provisions.

Business and Professions Code, Section 4180
The types of clinics that are eligible to obtain a general clinic permit from the board for drug rooms is expanded to include these clinics: operated by the United States or one of its departments or agencies, an Indian tribe or organization, primary care or community clinic open no more than 20 hours per week or a student health center clinic operated by a public institution of higher learning.

Business and Professions Code, Section 4200
"Pharmaceutical experience" is defined as that experience that an intern must gain during internship.

Business and Professions Code, Section 4200.1
An applicant who has passed the board's pharmacist licensure examination four times must take at least 16 semester units of pharmacy education.

Business and Professions Code, Section 4200.5
A category of "retired" pharmacist is created.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T.

Business and Professions Code, Section 4202(a)(3)
Once a pharmacist is licensed, he or she cannot retain pharmacy technician registration.

Business and Professions Code, Section 4231
A pharmacist must prove successful completion of continuing education required for license renewal.

Business and Professions Code, Section 4300 (c)
The board may issue a probationary license in any licensing category, not just to pharmacists.

Business and Professions Code, Section 4301(h)
Self-use, which poses danger to one-self – not just to the public- becomes grounds for discipline.

Business and Professions Code, Section 4301(p)
Any conduct that subverts or attempts to subvert a board investigation is grounds for discipline.

Business and Professions Code, Section 4303
The board may discipline nonresident pharmacies for a significant failure to provide adequate warnings or to label in compliance with California requirements.

Business and Professions Code, Section 4305.5
A board licensee is required to notify the board when a person in charge of various licensed entities leaves and makes failure to do so grounds for discipline.

Business and Professions Code, Section 4306.5
The board may discipline a pharmacist for misconduct involving the exercise of his or her professional skill, education, training, etc., even outside the normal practice of pharmacy (such as misconduct of pharmacists involved in health care coverage or policy judgements and decisions).

Business and Professions Code, Section 4307
Managers and administrators were added to those persons that can be prohibited from being a manager and administrator of a board license where the person was disciplined or knew of or knowingly participated in conduct for which a licensee was disciplined.

Business and Professions Code, Section 4313
The board must give consideration to evidence of rehabilitation, but that when evidence of rehabilitation and public protection are in conflict, public protection must take precedence.

Business and Professions Code, Section 4331
Wholesalers can be prosecuted for allowing a nonlicensee to take charge or for operating as a wholesaler without having an exemptee or pharmacist on the premises.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1997 CON'T

Business and Professions Code, Section 4333
Pharmacies are required to keep all records on the premises and available to inspection.

Business and Professions Code, Sections 4369 and 4370
The board is required to provide written notice to each pharmacist who is participating in the board's Pharmacist's Recovery Program of his or her rights and responsibilities and the possible consequences of noncompliance with the program. Also, the law requires when the board is notified that a participant has been terminated, the basis for the termination must be included in the letter.

Business and Professions Code, Section 4372
Program records for the Pharmacist Recovery Program may be disclosed to the extent that the underlying conduct is relevant to the basis on which the pharmacist was terminated from the program.

Business and Professions Code, Section 4402(e)
The board is authorized to cancel a license (except for pharmacists) if they are not renewed within 60 days of their expiration.

Health and Safety Code, Section 1261.5 and 1261.6
Skilled nursing facilities and intermediate care facilities licensed by the Department of Health Services are authorized to use automated drug delivery machines that are controlled and maintained by a licensed pharmacist and pharmacy.

Health and Safety Code, Section 11057 and 11375
Fenfluramine and its salts and isomers were removed from California's Schedule IV and repealed the prohibition of their sale, and will become operative only when those items are also removed from Schedule IV of the federal Controlled Substances Act. Flunitrazepam (or Rohyponol) was added to the Schedule IV controlled drugs.

1998

Business and Professions Code, Sections 4027 and 4052
A pharmacist can initiate drug therapy under protocol for patients receiving home health care service from a licensed home health agency.

Business and Professions Code, Section 4301
Cash compromise is restored to the list of grounds for discipline for unprofessional conduct.

Business and Professions Code, Section 4301.5
The license of a California pharmacist whose authority to practice pharmacy in another state is suspended or revoked by the other state or federal government, is automatically suspended or revoked for the duration of the suspension or revocation imposed by the other authority.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1998 con't

Business and Professions Code, Section 4322
The civil penalties and fines for those convicted of obtaining licensure by making false misrepresentations are substantially increased.

Health and Safety Code, Sections 11159.2 and 11167
A prescriber is not required to write a prescription for a Schedule II controlled substance on a triplicate prescription form for a patient who is terminally ill.

Health and Safety Code, Section 11166
A pharmacist must fill a Schedule II controlled substance within 14 days of it being written by the prescriber.

Health and Safety Code, Section 11352
Local public health officers are authorized to take action to stop the sale of dangerous drugs and dangerous devices by entities that are not licensed with the board.

1999

Business and Professions Code, Section 2725.1
Nurse practitioners are allowed to dispense Schedule III-V controlled substances in licensed clinics.

Business and Professions Code, Section 4022
California law is conformed to the definition of dangerous drugs in federal law.

Business and Professions Code, Sections 4040.5 and 4043
A "reverse distributor" is defined as a wholesaler.

Business and Professions Code, Section 4052
Pharmacists are permitted to adjust a patient's drug therapy in all outpatient pharmacy settings pursuant to a written protocol with a physician.

Business and Professions Code, Section 4056
Hospitals with 100 beds or less can dispense a 72-hour supply of prescription to outpatients if the prescriber feels that it is in the best interest of the patient and the hospital is located in a rural area.

Business and Professions Code, Section 4057
The list of dangerous drugs that are exempt from storage in a hospital pharmacy is moved to regulation.

Business and Professions Code, Section 4061
Nurse practitioners and physician assistants are permitted to sign for drug samples ordered by the supervising physician.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1999 CON'T

Business and Professions Code, Section 4076
Labeling requirements are changed to include the name of the nurse practitioner or physician assistant (under protocol with a supervising physician and surgeon) who writes a drug order pursuant to protocol.

Business and Professions Code, Section 4078
A pharmacist can label a prescription with false or misleading information for the purpose of clinical studies and dispensing placebos.

Business and Professions Code, Section 4102
The pharmacist's authority to perform skin puncture is expanded to include laboratory tests categorized as "waived" or "moderate."

Business and Professions Code, Section 4115
Pharmacy technicians are authorized to remain in the pharmacy during the pharmacist's absence and perform non-discretionary tasks.

Business and Professions Code, Section 4115.5
A pharmacy technician has 12 months instead of six to complete the practical training component of an education program.

Business and Professions Code, Section 4116
The board is required to adopt regulations permitting a pharmacy to remain open under certain conditions while the pharmacist takes lunch and rest breaks that are mandated by orders of the Industrial Commission and section 512 of the Labor Code.

Business and Professions Code, Section 4170
Nurse practitioners and physician assistants can hand drug samples to patients.

Business and Professions Code, Section 4200.5
Pharmacists do not need to return their wall certificate before receiving a retired pharmacist license.

Business and Professions Code, Section 4202
An applicant for pharmacy technician registration must possess a high school diploma or general education development equivalent.

Business and Professions Code, Section 4402
The board is granted discretion to cancel any board-issued license (except for pharmacists) 60 days after the license has expired.

Business and Professions Code, Section 4425
Pharmacies participating in the Medi-Cal program are required to sell prescription drugs to Medicare beneficiaries at the same price charged to Medi-Cal patients.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

1999 CON'T

Business and Professions Code, Section 4426
Department of Health Services is required to study the adequacy of Medi-Cal pharmacy reimbursement rates and track Medi-Cal participation changes that may be caused by providing prescription drugs to Medicare beneficiaries at Medi-Cal rates.

Health and Safety Code, Sections 11055, 11100 and 11377
Gamma-hydroxybutyrate and its immediate precursors are added to the list of Schedule II controlled substances.

Health and Safety Code, Section 11100
The sale of over-the-counter products containing ephedrine, pseudoephedrine, nonpseudoephedrine, or phenylpropanolamine (excluding liquid pediatric products for children) is limited to three (three-ounce) packages or nine grams for each single transaction.

Health and Safety Code, Section 11106
Those entities that are not licensed with the Board of Pharmacy or the Department of Health Services and who engage in the sale or distribution of ephedrine products must obtain a business permit from the Department of Justice and be registered with the Drug Enforcement Administration.

Health and Safety Code, Section 11165
The CURES program (to electronically track Schedule II controlled substance prescriptions) is extended to July 1, 2003.

2000

Business and Professions Code, Section 3041
The prescribing authority of optometrists who are certified to use therapeutic pharmaceutical agents is expanded to include other drugs for the treatment of eyes.

Business and Professions Code, Section 4019
Health care providers in a hospital are permitted to sign medication orders for another provider's patient.

Business and Professions Code, Section 4067
The board is permitted to issue citations and fines up to $25,000 per violation for dispensing a dangerous drug or dangerous device on the Internet without a valid prescription or provide a prescription via the Internet site without a good faith examination.

Business and Professions Code, Sections 4070 and 4071.1
Pharmacists no longer must reduce electronic data transmission prescriptions to writing if the computer systems used in the transaction meet specified criteria.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

2000 CON'T.

Business and Professions Code, Section 4119
Pharmacies are permitted to resupply ambulances with dangerous drugs and dangerous devices pursuant to an itemized written order from the emergency services provider. These dangerous drugs and dangerous devices are to be used exclusively in conjunction with ambulance services.

Business and Professions Code, Section 4125
All pharmacies are required to establish quality assurance programs designed to reduce the incidence of medication errors. Documents created in the course of these quality assurance programs are considered peer review documents and are not subject to discovery.

Business and Professions Code, Section 4139
The medical device retailer program is moved to Department of Health Services.

Health and Safety Code, Section 11056
Dronabinol is rescheduled from a Schedule II controlled substance to a Schedule III controlled substance.

Health and Safety Code, Sections 11161, repealed 11163 and 11164
The restriction on the number of triplicate prescription forms that a prescriber may order is eliminated as is the requirement that the triplicate be written entirely in the hand of the prescriber. The prescriber is only required to sign the triplicate. Also, the pharmacist can correct errors on a triplicate after consulting with the prescriber and then the prescriber is obligated to mail or fax the correction to the pharmacist within seven days.

Health and Safety Code, Section 11164.5
When federal law authorizes the electronic transmission of controlled substances, California will permit such transmissions.

Civil Code, Sections 56.07, 56.10, and 56.ll, and Health and Safety Code 12311
Existing law is amended to prohibit the disclosure of medical information between corporations and their subsidiaries and affiliates. Corporations and other organizations are also required to provide copies of patient records to patients at no charge. The appropriate release of patient medical information is specified and allows patients to insert written addenda into their medical records in response to any data the patient believes is incorrect or incomplete.

2001

Business and Professions Code, Sections 4033 and 4052.7
Pharmacies are allowed to repackage a previously dispensed medication upon the request of a consumer.

Business and Professions Code, Sections 4040, 4060, 4061, 4076, 4170, 4175
Certified nurse midwives are permitted to issue drug orders in the similar

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

2001 CON'T

Business and Professions Code, Sections 4050, 4051 and 4052
Pharmacists are authorized to perform clinical functions outside a pharmacy or other licensed health facility and can initiate drug therapy in accordance to protocol with a prescriber.

Business and Professions Code, Section 4052.1
The law is clarified relating to pharmacists performing clinical laboratory tests.

Business and Professions Code, Section 4052.5
Pharmacists can change the form of a medication (e.g., pill to liquid) without obtaining the prescriber's authorization if the change improves the patient's ability to comply with the prescribed drug therapy.

Business and Professions Code, Sections 4053, 4160 and 4196
The qualifications to become an exemptee for a licensed wholesale facility are changed to include a high school education, one year's paid work experience and the completion of a training program. In addition, exemptees are no longer restricted to work at the site where the exemption certificate has been issued.

Business and Professions Code, Section 4110
The board is permitted to issue a temporary pharmacy license at its discretion.

Business and Professions Code, Section 4115
The ratio of pharmacy technicians to pharmacists in community pharmacy settings is changed. For the first pharmacist on duty the ratio is one to one. For each additional pharmacist on duty, the ratio is one pharmacist to two pharmacy technicians. A pharmacist may refuse to supervise more than one pharmacy technician.

Business and Professions Code, Section 4119.2
Pharmacies can furnish epinephrine auto-injectors to school districts and county offices if specified conditions are met.

Business and Professions Code, Section 4126
A clinic and other eligible entities can contract with a pharmacy to have the pharmacy dispense drugs purchased in the 340B discount drug program to the clinic's patients.

Business and Professions Code, Sections 4127, 4127.1, 4127.2, 4127.3, 4127.4, 4127.5 and 4127.6
Pharmacies who compound injectable sterile drug products must obtain a separate license from the board. That license will require an annual inspection to ensure compliance with the guidelines on sterile compounding adopted by the board. The board can also close any sterile compounding operation if an investigation indicates an immediate threat to the public health or safety.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

2001 CON'T

Business and Professions Code, Section 4161
The definition of an out-of-state distributor is clarified.

Business and Professions Code, Section 4186
Nonprofit and certain government clinics licensed by the board may dispense drugs to their patients from an automated dispense device operated remotely by a pharmacist.

Business and Professions Code, Section 4200.5
The board's authority to issue a retired license is expanded.

Business and Professions Code, Section 4301
A cash compromise of any Medi-Cal violation is unprofessional conduct.

Business and Professions Code, Section 4400
The fee for the remodel of a pharmacy and the examination fee for an exemptee are eliminated.

Public Resource Code, Sections 15025 and 15026
Mercury fever thermometers can only be furnished pursuant to a prescription and all entities are required (including pharmacies) to obtain a hypodermic needle and syringe permit from the board if they dispense mercury fever thermometers.

* Gray shading indicates legislative changes sponsored by the Board of Pharmacy.

Regulation Changes
1997 To Present

1997

California Code of Regulations, Section 1706.2
Adds a 60-day time limit for the completion of application requirements.

California Code of Regulations, Section 1709.1
Adds the prohibition that a pharmacist-in-charge cannot serve concurrently as the sole pharmacist for a wholesaler, a medical device retailer or a veterinary food-animal drug retailer.

California Code of Regulations, Section 1714
Adds the ability of a non-pharmacist to possess a key to a pharmacy as long as the key is maintained in a tamper evident container.

California Code of Regulations, Section 1760
Adoption of the board's disciplinary guidelines.

California Code of Regulations, Section 1768
Adoption of requirements consistent with Business and Professions Code, Section 486 regarding the denial of an application and the evidence of rehabilitation that the board will consider upon reapplication.

California Code of Regulations, Section 1793.6
Emergency regulations allow a pharmacy technician to gain practical experience to meet the board's educational requirements for registration.

1998

California Code of Regulations, Section 1715.5
Establishes requirements for the electronic monitoring of Schedule II prescriptions. Pharmacies must report electronically each Schedule II prescription specific data: the full name and address of the patient, the gender and date of birth, the Drug Enforcement Administration number of the prescriber, the triplicate prescription number, the pharmacy prescription number, the pharmacy license number, the National Drug Code number, the quantity of the controlled substance, the diagnosis code; if available, the date of issue of the prescription and the state medical license number of any prescriber using the DEA number of a government exempt facility.

California Code of Regulations, Section 1725
Defines criteria for the remedial coursework that must be taken by applicants who have failed the pharmacist license examination four times.

1999

California Code of Regulations, Section 1749 and 1749.1
Board fees are reduced.

California Code of Regulations, Section 1783
Defines who is the "authorized" person within the meaning of Business and Professions Code section 4163 to order and receive shipments of dangerous drugs and dangerous devices.

2000

California Code of Regulations, Section 1707.4
A pharmacy can process refill prescriptions from other pharmacies at a centralized location.

California Code of Regulations, Section 1714.1
A pharmacy can operate during the temporary absence of a pharmacist.

California Code of Regulations, Section 1748.3
A medical device retail facility cannot be located at a private residence.

California Code of Regulations, Section 1775 and 1775.1
The executive officer can issue a citation and fine to a pharmacist who has failed to complete required continuing education.

California Code of Regulations, Section 1783
A manufacturer or wholesaler can furnish dangerous drugs and dangerous devices to an authorized person, who is defined, and specifies what the manufacturer or wholesaler must do to determine that a person is authorized to receive the dangerous drugs or devices.

2001

California Code of Regulations, Section 1707
Establishes requirements for a pharmacy that wants to store records off-site.

California Code of Regulations, Section 1714.5
Moves the list of dangerous drugs and dangerous devices that are not required to stored in a licensed hospital pharmacy to a regulation from a statute.

California Code of Regulations, Section 1715
Updates the self-assessment form with the current pharmacy laws.

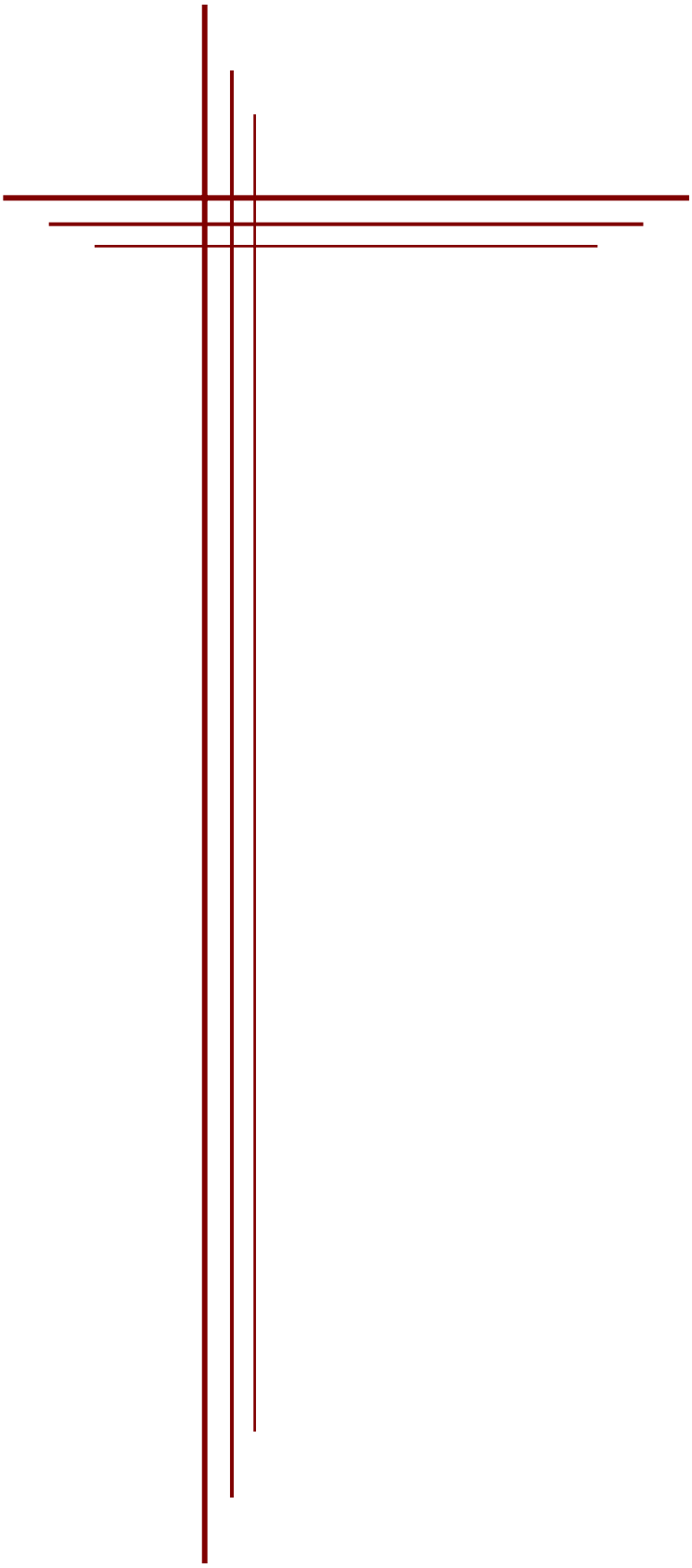
California Code of Regulations, Section 1717.3
A prescriber can check off more than one dangerous drug on a preprinted, multiple check off prescription blank as long as the prescriber has indicated on the prescription blank the number of dangerous drugs he or she has prescribed.

California Code of Regulations, Section 1775 and 1775.2
Expands the board's authority to cite and fine pharmacies and other board licensed entities to include all violations of pharmacy law.

2002

California Code of Regulations, Section 1711
Specifies the requirements for a quality assurance program. The program must be documented in written policies and procedures, the pharmacist must notify the patient and the prescriber that a medication error occurred, the findings of the quality assurance program must be used to develop pharmacy systems and workflow processes to prevent medication errors and the investigation and review of each medication error must commence as soon as possible, but no later than two business days from the date the medication error is discovered.

California Code of Regulations, Section 1707.2
Changes the content of the "Notice to Consumers" that must be posted in pharmacies or printed on receipts. The new content includes five questions patients should understand before taking prescription medication.



Blank Intentionally

OVERVIEW OF THE BOARD'S COMMITTEES

The Board of Pharmacy is overseen by an 11-member board, whose members are appointed by the Governor and Legislature. The board's operations and activities are guided by its strategic plan, which is revised each year with the active partnership of all board members and staff. Strategic planning and management are integral to the board's operations and successes.

The board's strategic plan establishes five standing committees through which the board articulates its goals and organizes its activities in pursuit of ensuring public health, safety and welfare, and to assure the provision of quality pharmacists' care. These five committees develop policy related to a board mission-related goal.

This section of the Sunset Report describes the five committees, their major accomplishments and the major changes undertaken since the last sunset review. The board formally organized itself into this committee structure during 1997/98.

The board's committees are:

- Communication and Public Education
- Licensing
- Enforcement
- Legislation and Regulation
- Organizational Development

Each of these committees is comprised of at two board members (Enforcement currently has three) and staff members who provide technical and administrative input and support. The committees are an important venue for ensuring that staff and board members share information and perspectives in crafting and implementing strategic objectives.

The board's committees allow board members and staff to discuss and conduct problem solving on issues related to the board's strategic goals. They also allow the board to consider options for implementing components for the strategic plan. The committees are charged with coordinating board efforts to reach board goals and achieving positive results on its performance measures.

The board president appoints board members to committees and designates one of the board members as the committee's chairperson. The chairperson coordinates the committee's work and ensures progress toward the board's priorities.

The committees refer policy decisions to the full board for a formal decision and vote. During this discussion, the public is encouraged to provide comments during the same segment as when the board discusses the issues for the first time as well as any subsequent discussions during board meetings.

At each board meeting, one of the board's committees holds a public meeting to encourage input and comment. Over the year, each committee has at least one such public committee meeting typically in conjunction with a board meeting; however, in 2002 public meetings of some committees began being held as stand-alone meetings — typically the Enforcement and Licensing Committees hold their meetings this way.

During the public committee meeting, comments from the public are strongly sought, and the meetings themselves are frequently public forums on specific issues before a committee.

Communication and Public Education Committee

Goal: Proactively provide relevant information to consumers and pharmacists.

VISIONARY LEADERSHIP – SIGNIFICANT ACCOMPLISHMENTS – MAJOR CHANGES

Committee Overview

The board has a public outreach program to advise consumers about the board and its consumer protection purpose, educate consumers about how to take their prescription medication appropriately, the health benefits or risks for compliance (or noncompliance) with drug regimens, and what questions consumers should understand before they take prescription or over-the-counter medications. The board has a diversity of consumer education materials, some in multiple languages. There is also a component to upgrade the knowledge of board licensees, and keep them advised about pharmacy law and board policies. The importance and structure of the board's public outreach program is described in the *Board Committees* section of this report under the Communications and Public Education Committee. An excerpt of this description is repeated on the next two pages.

The board has twice won national awards for its public education program. In 1999, the board won the *Paul G. Rogers Award* from the National Council for Patient Information and Education for outstanding leadership in the development, production, and dissemination of educational public services. The board's program was noted for its focus to enhance consumers' understanding of the value of high quality communication about medication, and the development and advancement of public policy to support improved medication communication.

In 1997, the board won the *Fred T. Mahaffey Board of the Year Award* from the National Association of Boards of Pharmacy for the state pharmacy board demonstrating outstanding leadership in protecting the public.

The board's communications and outreach program is divided into the following components:

- *Health Notes*, which is a compendium of up-to-date treatment methodologies and issues on a specific health care topic, published in a newsletter format for pharmacists and useful to other health care providers as well as to the public;
- Brochures, fact sheets, and newspaper columns to educate consumers about how to take their medications, the role of the board, how to file a complaint and health columns based on excerpts from *Health Notes* and other consumer brochures and health care issues;

- Public forums, including those where the board works with local activists to arrange health fairs, staffed by pharmacists to respond to patients' inquiries and covered by local media to disseminate the board's message to a wide audience; and
- Online availability of board publications to the public, licensees, and applicants at the board's Website (www.pharmacy.ca.gov).

The board has other public information functions, specifically:

- Producing four newsletters annually for licensees, advising them of new laws and regulations, board policies, compliance issues, and disciplinary actions taken by the board.
- Responding to press inquiries, which are becoming an ever-growing source of workload. Primary areas of inquiry in recent years have been the purchase of drugs over the Internet, patient privacy of prescription records, the number of prescription errors made by pharmacists, and the three patient deaths in 2001 due to a pharmacy's negligence in compounding medications.

Program Funding

Six years ago, the board implemented its public outreach program through a series of four budget change proposals (BCPs). Four BCPs were required because only a portion of the program was approved in any year, and then on a limited-term basis, and generally without any staff to perform the duties. Finally in July 2001, the board received one staff position in the budget; however, the October 2001 hiring freeze blocked the board's ability to fill the position (an individual had been interviewed but had not yet been offered the position), and the position will likely be lost due to cost cutting to reduce the state's deficit.

The board's public outreach is substantially impacted by the lack of this staff position, specifically in terms of the public outreach events the board coordinates and/or attends, and the board's ability to develop new consumer materials that responds to emergent issues.

The outreach events are important to the board to directly reach consumers face-to-face. But to extend the board's efforts to a much wider audience, the board seeks co-sponsorship of public information fairs from local media. By so doing, the board is able to obtain media coverage before, during and after the event, reaching a much wider audience than just those who attend the information fairs (such as "Talk to a Pharmacist" events). The board was highly successful in co-sponsoring these fairs during the late 1990s principally because two board members spent considerable time in coordinating the events. Without staff to coordinate these events, the board cannot and has not been able to co-sponsor them in the last two years.

Public Education

Public education is an essential element in the board's ability to provide for public protection. To do this the public needs to know that the Board of Pharmacy exists, that it is a consumer protection agency that will assist them with jurisdictional complaints, and most importantly needs to be contacted about the questionable behavior or practices of any board licensee.

Moreover, the board's public outreach program serves a second important function; for example, to educate consumers about pharmacy issues important to their health, how to take their prescription medications appropriately, and how to minimize their risks of medication errors.

The only way the board can provide optimal consumer protection is to assure that patients know the importance of following their prescribed drug therapy and how to advocate for their own interests and health in dealing with prescription drugs.

The board wholeheartedly agrees with a conclusion of the Little Hoover Commission in November 1998 in supporting the need for consumer education: "To be sure, government cannot pretend or aspire to protect all consumers in every transaction. That reality is among the reasons why consumer education is the best protection" *Little Hoover Commission, 1998.* The need for ongoing public education is essential for consumer protection in any area, but it is perhaps most necessary in the health care field where consumer protection has life saving benefits. The board has a number of consumer materials available to the public to educate and advise them about important issues.

In 2002 the board adopted regulation changes to its "Notice to Consumers," a collection of information which must be posted in every pharmacy or printed on a customer receipt. The revised information focuses on the questions patients should understand before taking any prescription medication. The board believes that by posting this information in a pharmacy where patients can see it, they will be better able to ask the questions they need to ask to take their medication more efficaciously.

Information / Education to Licensees

The board's newsletter, *The Script*, is highly valued by board licensees for its informative articles on pharmacy practice. After the last sunset review, the board's priority was to produce this newsletter quarterly. Until the retirement of the editor in December 2001, this occurred with several exceptions. However, the hiring freeze established in October 2001 has left the board unable to fill this position, and the board's existing staff will strive to produce at least one newsletter annually until the board is permitted to restore the position. The loss of momentum in producing this publication quarterly is a substantial disappointment to the board.

Health Notes monographs provide the board a unique method to educate pharmacists about current drug therapy for specific diseases and conditions. Since the initial publication of "Pain Management" in 1996, the board has produced five more – "Women's Health," "Anticoagulation Therapy," "Care of Children and Adults with Developmental Disabilities," "Alternative Medicines," and "Quality Assurance Programs." The board will

publish in early 2003 a seventh issue on "Geriatrics."

These issues also provide pharmacists with a means to obtain continuing education credit by submission of an examination of the monograph's content, enabling the board a method to ensure licensees learn this information. The information is also valuable to patients with an interest in the topic. Additionally the board will produce special consumer articles excerpted from these monographs once a public outreach staff person is hired.

Website

The board unveiled a redesigned and much more complex Website early in 2000, which among a number of other features offered a direct link with the Board of Pharmacy by which the public could contact the board's staff with general questions via the Internet. However, the board dismantled this link after the October 2001 hiring freeze because the board lacked the staff to maintain it. Once the freeze is removed and the board can fill its positions, the board will restore this interactive function. The board receives over one million hits per year on its website (1.6 million hits in 2001/02) and nearly 300,000 hits on its license verification feature.

New Consumer Materials

In 2000, the board produced a brochure for the public on SB 393 (Speier, Chapter 946, Statutes of 1999) that requires pharmacies to sell prescription drugs at Medi-Cal prices to Medicare patients who pay out of pocket for the medication. This brochure has received widespread distribution, reflecting the strong interest of the public in reducing their prescription drug costs.

In 2002, the board will produce a patient fact sheet on emergency contraception that was required by SB 1169 (Alpert, Chapter 900, Statutes of 2001). The board will absorb the workload and resources needed to develop this fact sheet since the budget change proposal to provide funding was denied by the Department of Finance.

Also, later in 2002, the board will print and distribute a new "Notice to Consumers" that by board regulation must be posted in the pharmacy or printed on the customer's receipt. The new notice contains the five questions patients should understand before taking any prescription medication, and will contain an 800 number for consumer inquiries to the board. This information aids patients in better medication compliance and will be available to them while they are in the pharmacy – where the information is needed.

In 1999, the board created a special task force to review patient compliance programs (where a pharmacy or other entity calls patients to remind them of the need to refill medication or switch to other drugs), the use of technology, and patients' privacy rights. One product of this task force was an article published in the board's April 2000 issue of *The Script* on the confidentiality of pharmacy information. The board will develop this article into another consumer factsheet.

Communication and Public Education Committee Meetings

1997 to Present

1997	
January	**Committee**-Coordinated Public Education Fair, Co-Sponsored with KGTV, San Diego -- "Talk With Your Pharmacist"
September 10	**Committee Meeting** • Identify any Master Service Agreements for Writers, Editors, Graphic Designers and Facilitators • Draft Specifications for Future Contracts to Develop, Design and Print Consumer Materials for Release for Bids • Reprint "Pain Management" *Health Notes*

1998	
February 23	**Public Meeting** • Plan for Summit of Health Care Payers and Providers • Preview Pharmacist Care Programs in Pharmacy Settings for Presentations at Summit
April 2 and 13	**Committee Meeting** • Planning and Arrangements for the Summit of Health Care Payers and Providers
April 23	**Public Meeting -- Summit Of Health Care Payers And Providers,** Convened by the Board of Pharmacy, U.S. Department of Health and Human Resources and in Cooperation With the California Health and Welfare Agency
May 18	**"Women's Health" Issue of *Health Notes* Published**
July 29	**Board Meeting Report** • Video Highlighting "Meet Your Pharmacist" Events Sponsored By the Board and Various Television Stations • Topics for Future *The Script* Newsletters • Update on Educational Activities

1998 (CONTINUED)	
OCTOBER 28	**Board Meeting Report:** • Publication of a Template for Sponsoring a Summit for Healthcare Payers and Providers – *Making the Case* • Consumer Column Data Presented

1999	
JANUARY 20	**Public Meeting during Board Meeting** • Status Report on *Health Notes, The Script*, Consumer Columns and "Talk to Your Pharmacist" Media Events • Board Participation in Statewide Diabetes Screening Day– January 23, 1999 • Topics for Future Health Notes, Newsletter Articles, Consumer Columns and Other Publications • Formation of a Medication Information Technology Task Force Planned
APRIL 22	**Committee Meeting** • National Council on Patient Information and Education Awards Board *Paul G. Rogers Medication Communications Award* • Articles for July 1999 Board Newsletter • *Health Notes* "Anticoagulation Therapy" issue • Development of Consumer Articles on Asthma and From "Women's Health" *Health Notes* Under Development • Development of "Making the Case" Nearing Completion • Development of Proposed Projects for 1999/00.
MAY 3	**Medication Information Technology Task Force Meeting** • Function and Purpose • Types of Automated Dispensing Machines in Use • Impediments and Incentives for Evolving Technology Use in Pharmacies
JULY 7	**Medication Information Technology Task Force** • Patient-Focused Care and Technology Issues • California's Privacy and Confidentiality Issues Related to Technology and Prescription Medication • Review of Federal Laws and Pending Legislation • How Financial Institutions Use Technology and Secure Consumer Records • Patient Compliance Programs

1999 (CONTINUED)	
JULY 19	**Board Meeting Report** • Anticoagulation *Health Notes* Printed and Mailed in June • Development of Care of Children and Adults with Developmental Disabilities *Heath Notes* Underway • Three Consumer Columns from Women's Health *Heath Notes* Being Developed • Columns on Asthma Prevention and Asking Questions May Save Your Life Are Distributed to Media • Invitation to Bid Being Prepared for a Survey of Consumers on the Effectiveness of the Board's Public Education Program • *The Script* Newsletter Planned for Publishing in August • UCSF Proposes a Joint Project with the Board to Produce a *Health Notes* on Alternative Medicines
OCTOBER 15	**Committee Meeting** • Updates on Care of Children and Adults with Developmental Disabilities *Health Notes,* Interagency Agreement Planned with UCSF to Develop Issue on Alternative Medicines • Request for Proposals Issued for a Survey of Consumers on the Effectiveness of the Board's Public Education Program. • The Script Newsletter Delayed Because Staff Assigned to Develop Budget Change Proposal • Pharmacy Lawbook Publication and Mailing to Pharmacies Planned for the End of the Year • SMART (Senior Medication Awareness and Training) Coalition Report

2000	
JANUARY 25	**Public Meeting During Board Meeting** • Legal Analysis and Discussion by the Board's Liaison Deputy Attorney General on the Law Governing Technology and Privacy, Including Amendments Made to the Confidentiality of Medical Information Act by SB 19 (Figueroa, Chapter 526, Statutes of 1999)
APRIL 12	**Board Meeting Report** • Final Page Layouts Completed for Care of Children and Adults with Developmental Disabilities *Health Notes* • April 2000 *The Script* at Printer • Consumer Survey Conducted in March; Report to the Board is due in Mid-April • Seven Consumer Columns Developed Over the Last Several Years in English and Four in Spanish Have Been Published in 3,832 Newspapers • Update on Strategic Goals
JULY 25	**Board Meeting Report** • Strategic Goals for 2000/01 • Care of Children and Adults with Developmental Disabilities Health Notes Published • July 2000 *The Script* Published • Consumer Survey and Develop Consumer Outreach Plan • Expand Information on the Board's Website • Pursue Budget Change Proposal for Staffing for Program
SEPTEMBER 28	**Committee Meeting** • Strategic Goals for 2000/01 • Budget of the Committee • *Health Notes* and *The Script* Update • Information Available on the Board's Website • Redesign the *Notice to Consumers* Poster and Feasibility of a Toll-Free Telephone Number • Reprint and Mailing the 2001 Pharmacy Lawbook to California Pharmacists • Planning for January 2001 Public Meeting

2001	
JANUARY 5	**Committee Meeting** • Status of Strategic Objectives for 2000/01 • Budget Report for 2000/01 • *Health Notes* Status and Publication Plans • January Public Meeting Agenda • Proposed Revisions to *Notice to Consumers* Poster • Expansion of Materials on the Board's Website • Translation of Materials into Additional Languages
JANUARY 24	**Annual Public Meeting of Committee** • Proposed Revisions to *Notice to Consumers* and Comments
APRIL 12	**Committee Meeting** • Status of Strategic Objectives for 2000/01 and Proposed Goals for 2001/02 • Proposed Revisions to *Notice to Consumers* • Expansion of Materials on the Board's Website • Heath Notes and *The Script* Updates • Proposed Presentation at the April 2001 Board Meeting by the Evergreen Project Regarding Senior Citizens and their Caregivers
JULY 25	**Board Meeting Report** • Proposed Revisions to *Notice to Consumers* Poster/Contract with Graphic Designer • Update on Committee's Goals for 2000/01 and 2001/02 • Budget Augmentation to Add One Staff Person to Public Outreach Achieved • Future Development and Production Schedule for *Health Notes*
OCTOBER 3	**Committee Meeting** • Status of Strategic Objectives for 2001/02 • Hiring of Associate Analyst for Public Outreach • *Notice to Consumers* Update • Publications Budget for 2001/02 • Future Development and Production Schedule for *Health Notes* – Alternative Medicines Issue Printed and Distributed • Public Outreach Activities

2001 (CONTINUED)	
DECEMBER 18	**Committee Meeting** • Status of Strategic Objectives for 2001/02 • Hiring Freeze Prevents Hiring of Public Outreach Staff • *Notice to Consumers* Update and Selection of Preferred Poster Design • Activity Plan to Develop Emergency Contraception Fact Sheet for Patients as Required by SB 1169 (Alpert, Chapter 900, Statutes of 2001) • Future Development and Production Schedule for *Heath Notes*

2002	
JANUARY 23	**Board Meeting Report** • Update on December 18, 2001 Meeting and Activities • Public Comment on Poster Design for *Notice to Consumers* • Public Comment on *Fact Sheet on Emergency Contraception* SB 1169
MARCH 26	**Committee Meeting** • Update on Strategic Objectives for 2001/02 • Proposed Strategic Objectives for 2002/03 • Hiring Freeze Prevents Filling of Newsletter Editor and Public Outreach Coordinator Positions • Status of *Notice to Consumers* • Status of *Emergency Contraception Fact Sheet* • Public Outreach Events – Planned Attendance • Future Development and Production Schedule of *Health Notes* and *The Script* • Required Consumer Labeling on OTC Products Effective May 2002
APRIL 25	**Board Meeting Report** • Regulation Hearing to Adopt Modifications to California Code of Regulation Section 1707.2 *Notice to Consumers* • *2002 Pharmacy Lawbooks* are Available • Update on Committee Activities and March 26, 2002 Meeting

2002 (CONTINUED)	
JULY 24	**Board Meeting Report** ♦ Update on *Notice to Consumers* Regulation ♦ Board to Co-Sponsor Six Public Forums with UCSF's Center for Consumer Self-Care and the Department of Consumer Affairs in 2002/03 ♦ Quality Assurance *Health Notes* to be Published and Distributed in August 2002
SEPTEMBER	♦ Quality Assurance Program's *Health Notes* Published

Blank Intentionally

Licensing Committee

Goal: Ensure the professional qualifications of pharmacists and establish minimum standards for board-licensed facilities.

VISIONARY LEADERSHIP – SIGNIFICANT ACCOMPLISHMENTS – MAJOR CHANGES

Committee Overview

Like the other board committees, the Licensing Committee began its meetings in 1997, and meets prior to each board meeting. This committee meets with executive staff, supervising inspectors, and key licensing unit personnel. This committee oversees the board's 12 major licensing programs that include about 76,000 licensees. The tables in the back of this section list the committee meetings that have been held and the agenda topics that were discussed until 2002. All committee-meeting summaries are provided to the board at each of its public meetings and at least one Licensing Committee meeting each year is a public meeting. In early 2002, a third board member was appointed to this committee and until June 1 when board membership on the committee changed back to two members all meetings of the Licensing Committee have been public meetings (after July 1, the Licensing Committee returned to a two-board member composition.) Additionally, last year the committee held five public meetings on pharmacy manpower.

The first issue addressed by the committee in 1997, was the delay in the processing of pharmacy applications. This delay was due to the major changes to the application process to ensure better protection of the public. The board needs to ascertain that it is not issuing a pharmacy permit to "hidden" owners for fraudulent purposes. The board added and revised forms so that it could obtain more detailed financial information in order to conduct a more thorough review and investigation of applicants.

The committee also has addressed other licensing matters such as:

- restocking of ambulances;
- recycling of nursing home drugs;
- repackaging of prescription medications by another pharmacy upon the patient's request;
- authorizing pharmacies to deliver prescription medications to a non-pharmacy location when the patient is not present; and
- allowing pharmacists to take continuing education by other approved healthcare program providers.

USE OF THE NATIONAL EXAMINATION [NORTH AMERICAN PHARMACIST LICENSURE EXAMINATION (NAPLEX)]

In January 2001, the Department of Consumer Affairs requested that the board explore the possibility of adopting the NAPLEX. Periodic review of the NAPLEX has been an element in the board's strategic plan and subsequent to the department's request, the board commissioned an independent audit of the NAPLEX by experts in professional licensing exams. The 2001 audit *(see List of Reports in Part I of this report)* found the NAPLEX to be a valid test of competence for entry to practice in pharmacy and that its development and administration conformed with requirements in California law for professional licensing examinations. The results of the audit were presented at the July 2001 Board Meeting and the board voted to support legislation (with two dissenting votes) that would establish the NAPLEX as the licensing examination for pharmacists in California.

The board believes that adopting the NAPLEX will remove an unnecessary administrative barrier to the practice of pharmacy in California while maintaining the high standard of competence consumers have come to expect. The current state exam restricts candidates to two opportunities to take the test each year, whereas the NAPLEX is offered year-round and reduces the waiting time for results from two months to days. The NAPLEX is the accepted examination for pharmacists in every other state and preserving a separate examination in California strongly discourages pharmacy graduates in other states to seek a California license. With the adoption of the doctor of pharmacy degree as the entry-level degree requirement by all U.S. pharmacy schools and the fact that all schools of pharmacy are held to the same standards and accredited by the same agency, the American Council on Pharmaceutical Education, there is no reason for California to continue its independent testing program.

However, as a condition of adopting the NAPLEX, the board also voted to support requiring pharmacy candidates to pass the Multi-State Pharmacy Jurisprudence Examination (MPJE). This test would be developed by the board to address California specific aspects of pharmacy practice and pharmacy law. The examination would be administered by the National Association of Boards of Pharmacy (NABP) through its testing network and would be available on a continuous basis at testing sites nationwide, but the board would retain the validation and scoring criteria for the exam.

Licensing Processes with NAPLEX

Candidates for licensure as a pharmacist begin by applying to a state board for licensure. The candidate then applies to the NABP to sit for the NAPLEX. On the application to the test (submitted to NABP), the appropriate board is designated as the "primary state." When NABP has a complete test application, the candidate's name is forwarded to board in the "primary state" who then determines if the candidate is qualified to take the examination under the applicable state law. The mechanism for this communication is a weekly listing of those candidates who have applied to take the examination and the board then marks those candidates who are eligible to take the exam and returns the list to NABP. Candidates who are not eligible are then rolled over to the next week's list.

Once the NABP receives notice that a candidate has been determined eligible to take the examination, it issues an Authorization to Test (ATT) form. The candidate may schedule an appointment to take the test at his or her convenience after receiving the ATT form. The test is administered at Prometric Testing Centers, which has approximately 300 testing centers nationwide, including 29 in California.

Examination results are sent to the NABP's testing contractor (The Chauncey Group which is a subsidiary of the Educational Testing Service) where the test is reviewed and subject to quality checks. The results are then forwarded to the NABP for final review. Test scores are available within three business days after taking the examination, which is substantially faster than possible with the board's current exam structure and process. Final scores are then forwarded to both the candidate and the relevant state board.

If the candidate passes the examination, then he or she is required to complete the licensure process mandated by the state board. If the candidate fails the examination, he/she may not take the examination again until after 91 days have elapsed. Applications to retake the examination are subject to the same procedure as initial applications.

Multi-State Pharmacy Jurisprudence Examination (MPJE)

Application processing for the MPJE is essentially the same as that for the NAPLEX. However, the MPJE is different because each individual state develops and submits its own questions for the MPJE examination. The NABP requires 400-500 questions to develop the MPJE for each state, and new questions must be developed every year. The questions need to conform to the set of competency statements developed by the NABP.

The NABP staff indicates that a California specific MPJE could be developed and implemented within six months.

License Transfer

The NABP also provides a "license transfer" service for pharmacists. Essentially, the NABP acts as a clearinghouse for license transfer information. The NABP requires applicants to submit a range of information (including disciplinary history) and compiles a full transfer application. Upon completion, the license transfer application is forwarded to the board requested by the applicant. The board then evaluates the application and makes the determination regarding the issuance of a license. The NABP makes no judgments or determinations regarding the issuance of a license.

Fees

Adopting the NAPLEX and the MPJE would increase the fees for initial licensure. Currently it costs those candidates taking only the California examination $270 ($155 exam fee, $115 license fee) to take the exam and obtain a license. Adopting the NAPLEX would increase that to $760 ($360 NAPLEX fee, $130 MPJE fee, $155 exam fee, $115 license fee), which is a 281 percent increase.

This fee increase is mitigated by several factors. First, the NAPLEX is a 4.25 hour exam, as opposed to the current board exam that is nine hours spread over two days. For those

candidates who do not live near the San Francisco Bay Area, taking the exam also requires the cost of food, travel, and an overnight stay in a hotel. Those travel costs apply for most candidates and are at least $200, and costs exceeding $400 are entirely reasonable. The NAPLEX is given in one day and with 29 testing centers in California alone; it is difficult to imagine a candidate who could not easily drive to a testing center for the exam. This eliminates the food, hotel, and most travel costs associated with the current California exam.

JOB ANALYSIS – CALIFORNIA PHARMACIST LICENSURE EXAMINATION

In 2001, the Board of Pharmacy (through its Competency Committee) conducted a job analysis of pharmacist practices, which is required as part of the validation process for the pharmacist licensure examination. The Competency Committee developed a questionnaire that was mailed to over 2,000 pharmacists throughout California. Half of the surveys went to pharmacists licensed more than five years, and the other half to pharmacists licensed less than five years. The committee received over 900 responses, which were used to compile a new content outline. The committee used the content outline to revise the examination and develop new questions. The revised format was administered in June 2001. The next job analysis is planned for 2004.

PHARMACY MANPOWER TASK FORCE -- A WORKING GROUP TO ENSURE PATIENT ACCESS TO PHARMACIST'S CARE AND PRESCRIPTION SERVICES

The California State Board of Pharmacy conducted a series of five Manpower Task Force Meetings throughout the state during calendar year 2001. The purpose of the task force was to address the pharmacist shortage in California and generate a set of proposed solutions to be submitted to the board for review and action. All task force meetings were open to the public. The task force issued its final report in November 2001 and the board considered the recommendations at its January 2002 board meeting.

The task force was comprised of 15 members that included two board members who were also members of the Licensing Committee. The 15-member task force included representatives from the four California schools of pharmacy, the California Pharmacists Association, the California Society of Health-System Pharmacists, three pharmacist labor organizations – the Guild for Professional Pharmacists, the California Employee Pharmacists Associations, and the United Food and Commercial Workers, Local 324, the California Retailers Association, the California Association of Health Plans and a consumer member.

The task force considered 27 proposed solutions and made recommendations on all but 11. Through its Licensing Committee, the board reviewed the recommendations and took some type of action on each proposed solution, such as adding the proposed solution to its strategic plan for 2002/03, taking a support position on the proposal (which could require legislation for implementation), or pursuing a regulation change.

LICENSURE OF STERILE COMPOUNDING PHARMACIES

Due to three patient deaths and significant harm to 33 others in mid 2001, Senators Torlakson and Figueroa sponsored legislation (SB 293, Chapter 827, Statutes of 2001) to strengthen the board's ability to regulate pharmacies that compound sterile injectable medications. These patients were harmed when they were injected with a bacteria-contaminated steroid that resulted in them contracting meningitis.

The legislation requires pharmacies that compound injectable sterile drugs to obtain a special pharmacy license and comply with the standards developed by the board. The law also prohibits pharmacies from undertaking sterile compounding until the board has inspected them and has found the facilities, equipment, processes, and training must meet California standards to ensure the safety of the pharmacy's medications.

The licensure and standards requirements are to become effective no later than July 1, 2003, or earlier should the board adopt the standards sooner. The board released a draft of the proposed standards at its January 2002 board meeting and held an informational hearing on them at the board's April 2002 meeting. Due the comprehensiveness and complexity of the proposed regulations, the Licensing Committee held another informational hearing at its committee meeting on June 24, 2002, and another informational hearing at the July 2002 board meeting. The board's proposed standards are set for a regulation hearing in October 2002.

To implement the program, the Department of Finance approved an augmentation of $309,000 for 2002/03 and $272,000 ongoing for one supervising inspector, one inspector, one technician, and operating expenses. Securing the needed staffing for this additional and significant program was difficult due to the state's budget deficit for fiscal year 2002/03.

CENTRAL REFILL PHARMACY

California was the first state to authorize the refill of prescriptions at a central pharmacy location. To allow this practice, the board adopted a regulation that became effective in 1999. A pharmacy can contract with other pharmacies to refill prescriptions at a central, highly automated location and then return the filled prescription to the original pharmacy for dispensing to the patient. The regulation specifies the conditions that both pharmacies must meet to ensure patient safety.

The board initiated activities to update pharmacy law to allow central refill to take place. These central refill centers are highly automated and fill thousands of prescriptions daily.

LICENSING PROGRAM CHANGES

Pharmacy Technicians

Several changes have been made to the pharmacy technician program since its implementation in 1992 and since the board's 1996 sunset review. Now all pharmacy technicians must be registered in order work in a community or hospital pharmacy setting. The initial legislation

only required registration for community pharmacy technicians. The licensing requirements were changed to require either graduation from high school or a GED certificate. Pharmacy technician students enrolled in a technician training program operated by a California public postsecondary education institution or by a private postsecondary vocation institution approved by the Bureau of Private Postsecondary and Vocational Education may complete a 120-hour externship in a community or hospital pharmacy as a "trainee" during a 12-month period.

Medical Device Retailer Program

Through legislation, the Board of Pharmacy agreed to transfer the medical device retailer program to the Department of Health Services. This program required that a facility be licensed if it dispensed "dangerous devices." Dangerous devices require a prescription from a prescriber to be dispensed to a patient. Sponsors of the legislation wanted to expand the scope of the licensure program to include a broader spectrum of medical supplies (not just those that require a prescription) in an effort to combat fraud. This transfer took effect on July 1, 2001.

Wholesalers / Exemptees

A business that wholesales prescription drugs and/or prescription devices to pharmacies and other licensed health professionals or entities must be licensed with the board. The wholesale facility must place in charge of the operations either a licensed pharmacist or a person that is "qualified" as determined by the board. Historically, the board determined that qualification by examining applicants on the law. Moreover, the permit issued to the "exemptee" was issued to a specific wholesale location; it was not issued to the individual. So if an exemptee's place of employment changed, a new license was needed.

In 2001, the board sponsored a legislative change to simplify the process. The exemptee license is now issued to the individual; the individual must have at least a high school education or GED certificate, one year of paid experience related to the distribution of prescription drugs and prescription devices and have completed a training course specified by the board. The wholesale facility also must designate an "exemptee-in-charge" who is responsible for the daily operations of the facility including compliance with pharmacy law. The experience requirements replaced the examination of applicants for exemptee licenses as well.

The board also amended the definition of "wholesaler" to include a reverse distributor. A reverse distributor is an entity who acts as an agent for pharmacies, wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable prescription drugs.

Mercury Fever Thermometers

Legislation that became effective July 1, 2002, requires that a mercury fever thermometer may only be furnished pursuant to a prescription and requires that all entities (including pharmacies) that dispense these thermometers to obtain a hypodermic needle and syringe permit from the board.

Retired Pharmacist's License

The board sponsored legislation to allow pharmacists seeking to retire from the practice of pharmacy (and without revoked licenses) to change their license status to retired. An individual with a retired pharmacist license cannot practice as a pharmacist and must retake the licensure examination to restore his or her license to active status.

General Licensing Program Changes

The Board of Pharmacy sponsored or supported additional legislation that made general changes to improve and strengthen the board's licensing programs. These changes included:

- authority to cancel a license after 60 days for failure to renew a license (the exception is for a pharmacist's license which is cancelled after three years),
- implementation of Live Scan submission of fingerprint cards and federal background checks for all licensees, and
- authority to issue a temporary permit to an entity, and requirements that applicants for a pharmacist license must take 16 units of education in a school of pharmacy after they fail the licensure exam four times.

Blank Intentionally

Licensing Committee Meetings

1997 to Present

1997	
August 29	**Committee Meeting** • Planning Meeting – Staff Provided Overview of Various Licensing Programs, Workload and Processing Times
December 11	**Committee Meeting** • Review of Pharmacy Application Process and Established 60-day Goal to Issue License

1998	
February 10	**Committee Meeting** • Review of Strategic Plan and Performance Measures – Reported on Processing Times
April 22	**Committee Meeting** • Continued the Review of Pharmacy Application Process and Performance Measures
May	**Public Committee Meeting** • Requests for Proposals for Changes to the Board's Various Licensing Programs and Processes for Future Strategic Direction
October 13	**Committee Meeting** • Review of Strategic Plan • Limited Liability Companies • Regulation of Alternative Pharmacy Sites: Refill and Call Centers • Waiver Parameters for Off-Site Storage of Records • Restocking of Ambulances with Supplies and Medications • Implementation of FDA Modernization Act of 1997 • Disease State Management Exams • Recycling of Nursing Home Drugs • Use of NAPLEX • Regulation of Reverse Distributors • NABP Pharmacist Continued Competency Assessment

1999	
JANUARY 5	**Committee Meeting** • Report of Application/Licensing Statistics • Processing Timeframes and Workload • Waiver Parameters for Off-Site Storage of Records • Restocking of Ambulances • Implementation of FDA Modernization Act of 1997 • Review of NAPLEX • Recycling of Nursing Home Drugs • Report on CE Program • UCSF Technician Study • Extension of Technician Externship to 1 Year • Establishment of Telepharmacy Network • Drive Through Pharmacies – Consultation Policy • Examination Requirements for Non-Pharmacist Pharmacy Owners • Dangerous Drugs Exempt from Storage in a Hospital Pharmacy • Update of CCR 1751.11 – Dangerous Drugs in an Emergency Kit • Practice of Pharmacy on the Internet • Clarification of Pharmacist's Scope of Practice Outside a Pharmacy • MDR Location Restriction
MARCH 6	**Committee Meeting** *Old Business:* • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Waiver Parameters for Off-Site Storage of Records • Restocking of Ambulances • Implementation of FDA Modernization Act of 1997 • Review of NAPLEX • Recycling of Nursing Home Drugs • UCSF Technician Study • Establishment of Telepharmacy Network • Examination Requirements for Non-Pharmacist Pharmacy Owners • Dangerous Drugs Exempt from Storage in a Hospital Pharmacy • Update of CCR 1751.11 – Dangerous Drugs in an Emergency Kit • Practice of Pharmacy on the Internet *New Business:* • Evaluation of Foreign Pharmacists' Education by Outside Agency • Review of General Correspondence on: Electronic Health Records, Management of Medications by Nurses, Pharmacist Performed Skin Puncture, Pharmacist e-Mail Addresses, Automated Pharmacy Stations, Revisions to Registration Requirements for Pharmacy Technicians

1999 (CONTINUED)	
APRIL 27	**Committee Meeting** *Old Business:* • Report of Application/Licensing Statistics, Processing Timeframes, and Workload Processing Timeframes and Workload • Waiver Parameters for Off-Site Storage of Records • Restocking of Ambulances • Implementation of FDA Modernization Act of 1997 • Review of NAPLEX • Recycling of Nursing Home Drugs • UCSF Technician Study • Establishment of Telepharmacy Network • Examination Requirements for Non-Pharmacist Pharmacy Owners • Dangerous Drugs Exempt from Storage in a Hospital Pharmacy • Update of CCR 1751.11 – Dangerous Drugs in an Emergency Kit • Practice of Pharmacy on the Internet *New Business:* • Review of CCR 1732.2 – Non Recognized CE Providers • Proposed Certificate Programs in Disease Management • Revised Strategic Plan
JULY 1	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Recycling of Nursing Home Drugs • Restocking of Ambulances • Limited Liability Companies • USP Requirements for Monitoring Devices for Time-Temperature & Humidity • Centralized Automated Dispensing for Hospital Pharmacy
JULY 27	**Public Committee Meeting** • Pharmacy Practice Outside the Traditional Pharmacy • Internet Pharmacy • Pharmacist Consultation • Call Centers
SEPTEMBER 16	**Public Committee Meeting** • Pharmacy Manpower Forum • Open Discussion on the Pharmacist Shortage in California and Suggested Ways to Address Pharmacy Staffing Issues
SEPTEMBER 16	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Recycling of Nursing Home Drugs • FDA-MOU on Pharmacy Compounding • USP Requirements for Monitoring Devices • Proposed Legislation Regarding Pharmacy Practice on the Internet, Automation Devices and Demonstration Projects

2000	
JANUARY 6	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Proposed Legislation on Ambulance Restocking • Waiver of Licensing Requirements – B&P 4118 • Pharmaceuticals and Indigent Care Program • Request to Require Manufacturers to Accept Expired Drugs • FDA Regulations Implementing the Prescription Marketing Act of 1987 • Industrial Use of Hypodermic Needles and Syringes
JANUARY 25	**Public Pharmacy Manpower Forum Meeting** • Open Discussion on the Pharmacist Shortage in California and Suggested Ways to Address Pharmacy – Staffing Issues
MARCH 28	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Pharmacy Manpower Issues • Proposed CCR 1714.5 – Dangerous Drugs Exempt from Storage • Compliance Policy Regarding Electronic Transmission of Prescriptions • Regulation of Nuclear Pharmacies • Pharmacists Call-Centers • PIC Changes Not Reported • Implementation of MDR Home Location Prohibition • Strategic Planning
JUNE 19	**Committee Meeting** • Report on Application/Licensing Statistics, Processing Timeframes and Workload • Use of Automated Devices/Technology • Pharmacy Manpower Issues • Job Analysis of Pharmacist Licensure Exam • Review of NAPLEX • Licensure of Pharmacies on Indian Reservations • Waiver Request of CCR 1717(e) • Licensure of Out-of-State Pharmacists Providing Care to California Patients • Implementation of "Telephone Medical Advice Service Providers" • Strategic Planning • Medi-Cal Fraud – Pharmacy Licensure
OCTOBER 3	**Committee Meeting** • Report on Application/Licensing Statistics, Processing Timeframes and Workload • Use of Automated Devices/Technology • Pharmacy Manpower Issues • Job Analysis of Pharmacist Licensure Exam • Review of NAPLEX • Licensure of Pharmacies on Indian Reservations • Federal Regulations Regarding 340B Drugs • Strategic Goals for 2000-01 • Implementation of Live-Scan Fingerprint Clearances • Transfer of MDR Program to DHS (AB 1496)

2001	
JANUARY 11	**Committee Meeting** • Report on Application/Licensing Statistics, Processing Timeframes and Workload • Use of Automated Devices/Technology • Pharmacy Manpower Issues • Job Analysis of Pharmacist Licensure Exam • Review of NAPLEX • Licensure of Pharmacies on Indian Reservations *Proposed Legislation* • Issuance of a Temporary Pharmacist License to a Pharmacist Practicing in a Pharmacy Located on Land of a Recognized Indian Tribe • Remote Pharmacy Sites • Out-of-State Distributors • Changes to Wholesale/Exemptee Provisions • Dispensing of 340B Drugs by Pharmacies • Requests for Waiver of CCR 1717(e) • Proposed Regulation to Define Wholesaling
JANUARY 23	**Public Pharmacy Manpower Task Force Meeting** • A Facilitated Discussion on Proposed Solutions to Pharmacy Manpower Shortage and other Means to Ensure Patient Access to Pharmacist's Care and Prescription Services
APRIL 4	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Review of NAPLEX • Report on Pharmacy Manpower Task Force • Request for Waiver of CCR 1717(e) • Review of Intern Program • Proposed Strategic Objectives for 2001/02 • Implementation of Waiver Program for Off-Site Storage of Records • Self-Assessment Program Update
APRIL 27	**Public Pharmacy Manpower Task Force Meeting** • A Facilitated Discussion on Proposed Solutions to Pharmacy Manpower Shortage and other Means to Ensure Patient Access to Pharmacist's Care and Prescription Services
JUNE 8	**Public Pharmacy Manpower Task Force Meeting** • A Facilitated Discussion on Proposed Solutions to Pharmacy Manpower Shortage and other Means to Ensure Patient Access to Pharmacist's Care and Prescription Services

2001 (CONTINUED)	
JUNE 28	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Report on Pharmacy Manpower Task Force • Review of NAPLEX Audit • Request for Waiver of CCR 1717(e) • Review of Strategic Objectives for 2001/02 and Activities for Implementation
JULY 24	**Public Pharmacy Manpower Task Force Meeting** • A Facilitated Discussion on Proposed Solutions to Pharmacy Manpower Shortage and other Means to Ensure Patient Access to Pharmacist's Care and Prescription Services
OCTOBER 4	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Report on Pharmacy Manpower Task Force • Review of Proposed MOU Regarding Use of NAPLEX and MPJE in California • Proposed Amendment to CCR 1717(e) to Allow Delivery of Prescriptions to Non-Pharmacy Locations • Requests from Pharmacy to Wholesale a Specific New Drug to Hospitals in Emergency Situations • Request for Multi-Site Dispensing by a Hospital
OCTOBER 10	**Public Pharmacy Manpower Task Force Meeting** • A Facilitated Discussion on Proposed Solutions to Pharmacy Manpower Shortage and other Means to Ensure Patient Access to Pharmacist's Care and Prescription Services
DECEMBER 20	**Committee Meeting** • Report of Application/Licensing Statistics, Processing Timeframes and Workload • Pharmacy Manpower Task Force Report • Request for Waiver of Pharmacy Sink Requirement • Request for Waiver of CCR 1717(e) • Implementation of SB 293 – Licensure of Compounding Pharmacies • Implementation of New Wholesaler/Exemptee Requirements • Request to Reconsider Fee for Review of CE Provided by a Non-Recognized Provider

2002	
MARCH 7	**Public Committee Meeting** ♦ Discussion and Recommendations of the Pharmacy Manpower Task Force ♦ Proposed Guidelines for Wholesaler Exemptee Training Program ♦ Proposed Strategic Objectives for 2002/03
JUNE 24	**Committee Meeting** ♦ Develop an Implementation and Work Plan for Board Action Regarding Pharmacy Manpower Task force Proposed Solutions ♦ Review Goal Statement and Strategic Objectives for 2001/02 and 2002/03 ♦ Requests for Waiver of CCR 1717(e) – Delivery of Prescription Medications to Nonpharmacy Locations ♦ New FDA Compounding Guidelines

Blank Intentionally

Legislation and Regulation Committee

Goal: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy

VISIONARY LEADERSHIP – SIGNIFICANT ACCOMPLISHMENTS – MAJOR CHANGES

Committee Overview

The committee's principal task is to shape legislation governing pharmacy practice to conform to the demands of a rapidly changing health care system while preserving consumer safety. This task is complicated by the often-complex interplay of numerous state and federal laws that govern the distribution of prescription drugs (e.g., the Pharmacy Law, the California Uniform Controlled Substances Act, the Sherman Food, Drug and Cosmetic Act, the United States Food, Drug and Cosmetic Act, the United States Controlled Substances Act). The rapid advance of health care technology (e.g., automation, communications, and clinical innovations), workforce issues (e.g., persistent shortage of pharmacists, geographic and socioeconomic imbalances in the distribution of pharmacies and pharmacists), demographic changes (e.g., aging population, rapidly increasing numbers of consumers from distinct racial, ethnic and linguistic backgrounds), and marketplace issues (e.g., consolidation, growth in chain pharmacies, direct-to-patient advertising of prescription medications, supermarket/mass marketer pharmacies, mail-order pharmacies, rapidly rising drug costs, and rapid increases in prescription volumes) increase the complexity of the board's policymaking activities.

In formulating its policymaking agenda, the board recognized and built upon a growing body of literature that has highlighted the costs (both human and economic) of medication errors and that has demonstrated the value of pharmacist intervention in providing drug therapy both in terms of improved outcomes and increased cost effectiveness. The passage of SB 1339 (Figueroa, Chapter 677) in 2000 (requiring pharmacies to establish quality assurance programs to evaluate prescription errors) and AB 826 (Cohn, Chapter 262) in 2001(allowing pharmacists to initiate prescription drug therapy under protocols with prescribers and to practice pharmacy wherever the pharmacist is, not just in a licensed facility) are both notable examples of the board's responses to these issues. These measures reflect the multi-dimensional nature of consumer protection.

Consumer protection is cognizable as more than licensing standards and enforcement actions. It includes devising and implementing prevention strategies and eliminating unnecessary barriers to access to vital health care resources. Both of these themes are evident in the priority legislation sponsored by the board since its last sunset review.

In the last two years alone, the board has successfully sponsored significant legislation to make sweeping changes that benefit the provision of pharmacists' care to patients, fulfilling the board's vision of "Healthy Californians through Quality Pharmacists' Care." The cumulative impact of this body of legislation has fundamentally restructured pharmacy for the future, and reflects magnitude of the board's commitment to visionary leadership.

In 2000, the board sponsored SB 1339 (Figueroa, Chapter 677, Statutes of 2000) to require pharmacies to implement a quality assurance program to prevent prescription errors from recurring and exempts quality assurance documents from discovery. This legislation was pursued in response to the fact that prescription errors are the most common consumer complaint received by the board and growing evidence in the healthcare literature supported the development of "blame free" continuous quality improvement efforts. The board initiated its quality assurance efforts in 1999 with a proposed regulation mandating quality assurance programs that received widespread opposition from the industry and profession. That opposition was grounded in concerns that quality assurance documents would be used against pharmacies and pharmacists in civil suits arising from prescription errors.

In 2001, the board sponsored AB 826 (Cohn, Chapter 262, Statutes of 2001), which permits pharmacists to perform clinical and consulting functions outside a licensed pharmacy and to initiate a patient's drug therapy in all practice settings under protocol.

In 2001, the board sponsored SB 293 (Torlakson and Figueroa, Chapter 827, Statutes of 2001), which requires a separate license for any pharmacy that compounds injectable sterile drugs and requires the board to adopt standards for compounding injectable sterile drugs. This bill was introduced in response to negligence in compounding medication that caused three deaths and multiple hospitalizations.

In 2000, the board sponsored AB 2018 (Thomson, Chapter 1092, Statutes of 2000) to make CURES (the electronic tracking of Schedule II controlled substances) permanent and eliminate the triplicate prescription requirement for Schedule II controlled substances. However, these provisions were opposed strongly by law enforcement groups and the bill was amended instead to reform the process for issuing triplicates. The changes removed several restrictions on the issuance of triplicates by the Department of Justice that had proven problematic.

In 2001, SB 340 (Speier, Chapter 631), sponsored by the board, allows a clinic eligible for participation in the federal 340B program to contract with a pharmacy to dispense 340B drugs to patients of the eligible clinic. The 340B program permits non-profit clinics to purchase drugs for their patients at dramatic discounts and provide those drugs to their patients at reduced cost. Contract pharmacy arrangements permit more clinics to participate in this program because many smaller clinics lack the resources to operate a drug dispensary.

In 2001, AB 809 (Salinas, Chapter 310), sponsored by the board, permits the use of automated dispensing devices by licensed clinics that are controlled and operated by an off-site pharmacist.

OTHER LEGISLATIVE ACTIVITY

In 1996, the board sponsored a technical reorganization and recodification of Pharmacy Law (AB 2802, Chapter 890, Statutes of 1996) to make it more coherent and eliminate archaic provisions. That bill was followed by a substantive update of Pharmacy Law (SB 1349, Chapter 549, Statutes of 1997) that made over 75 different changes to align pharmacy law and current practice.

The committee has continued the effort to keep pharmacy law current with changes in the healthcare delivery system by participating in the omnibus bills sponsored by the Business and Professions Committee. The annual omnibus measure provides an efficient means to perform ongoing maintenance of pharmacy law, and the board is grateful to the Business and Professions Committee for its commitment of valuable staff time and resources to author the omnibus bills. In 2001, provisions in the omnibus bill sponsored by the board reshaped and restructured the licensing of exempt individuals who oversee drug wholesalers in place of a pharmacist.

In 2000, the board sponsored a conference on CURES to consider the direction of California's policy regarding the electronic monitoring of schedule II controlled substances. Participants included federal and state law enforcement agencies, regulatory agencies, the legislature, professional health associations, consumers, pain management specialists, pain management advocates, and consumers. This conference laid the groundwork for what was introduced as AB 2018. This bill was a major board-sponsored effort to repeal the triplicate and implement CURES permanently as a prescription monitoring program modeled on the program operated by the Nevada Board of Pharmacy.

Also in 2000, the board supported AB 1496 (Olberg, Chapter 837) which transferred the medical device retailer program to the Department of Health Services. 2000 also witnessed the enactment of SB 1828 (Speier, Chapter 681), also supported by the board, which established a $25,000/violation fine for the illegal dispensing of drugs via the Internet.

In 2001, the board sponsored AB 108 (Strom-Martin) that would have adopted the national pharmacist examination (NAPLEX) in California. However, the bill failed due to substantial industry opposition. Assemblywoman Strom-Martin reintroduced the issue in 2002 as AB 2165.

In 2002, the board is sponsoring AB 2655 (Matthews) to extend the sunset date for CURES for five years and to permit provider access to CURES profiles for their patients.

REGULATIONS

The board has followed similar modernization themes in its rulemaking activity. However, by its nature, the rulemaking process is more reactive than the legislative process. Nevertheless, the board was the first in the nation to adopt a rule permitting the development of central refill pharmacies. Such pharmacies take refill requests from multiple storefront pharmacies and fill them at a central (usually highly automated) facility. That central facility then returns the filled prescription to the storefront pharmacy for dispensing to the patient.

The board is also the first board in the department to adopt regulations to issue citations and fines for violations of the Confidentiality of Medical Information Act (CMIA). The CMIA was amended by SB 19 (Chapter 526, Statutes of 1999) to permit agencies to impose penalties for its violations by administrative fine. The board adopted this regulation in January 2002.

Other significant regulations promulgated by the board since the last sunset include:

- 1997 Adopted an emergency regulation to permit those enrolled in a pharmacy technician-training program to obtain practical experience in a pharmacy -- providing a means to obtain the experience required for registration as a pharmacy technician.
- 1998 Adopted emergency regulations, which mandated computerized pharmacies to implement the Controlled Substance Utilization Review and Evaluation System (CURES). Pharmacies that met the timeframe for implementing CURES (reporting the data electronically to the vendor) received a one-time license renewal fee reduction of $75.
- 1999 Adopted regulations to authorize the refill of prescriptions from other pharmacies at one centralized pharmacy location.
- 1999 Implemented the self-assessment regulation that required all pharmacies to perform a self-inspection of its facilities, aiding pharmacies in complying with federal and state pharmacy law. The self-assessment must be performed every time a new pharmacy opens, when there is a change in the pharmacist-in-charge, and otherwise every two years.
- 1999 Adopted emergency regulations to permit the temporary absence of pharmacists from a pharmacy for breaks and lunch periods under new provisions of the Labor Code and orders of the Industrial Welfare Commission.
- 1999 Reduced fees to the levels that were in effect prior to July 1, 1995, because of the return of $5.4 million that was transferred to the state's General Fund in 1991/92.
- 2001 Adopted regulations to require every pharmacy to implement a quality assurance program to prevent prescription errors from reoccurring. California was the first state in the nation to do this.
- 2002 Adopted a regulation that permits the board to issue a fine up to $25,000 for each violation of dispensing prescription drug via an Internet prescription and without a good faith medical examination by a prescriber.
- 2002 Adopted a regulation that permits the board to issue a fine up to $250,000 for each violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
- 2002 Adopted a regulation updating the Notice to Consumers posted in each pharmacy.

In 2002, the board will be considering regulations establishing standards for sterile compounding pursuant to SB 293 (Torlakson and Figueroa, Chapter 827, Statutes of 2001). The board is currently preparing a rulemaking to reorganize and make technical updates to existing board regulations. This rulemaking will be submitted as a "Section 100" filing that allows technical corrections but not substantive changes to existing regulations.

Legislation and Regulation Committee Meetings

1997 to Present

The following table describes the Legislation and Regulation Committee meetings since 1997. In the interest of non-duplication, a legislative display found in the *Overview* section at the front of this report (*Legislation and Regulation Changes to California Law, 1997 to Present)* list statutory changes by year to pharmacy law made by the California Legislature and regulation changes adopted by the board. These items are not listed separately below.

1997	
November 11	**Public Committee Meeting** • Obtain Comments from the Public on Necessary New Legislation or Regulations for 1998

1998	
March 3	**Committee Meeting** • Governor's Office Request to Promulgate Regulations Barring Illegal Aliens from Licensure by State Agencies (Personal Responsibility and Work Opportunity Reconciliation Act of 1996) • CURES Regulations • Regulations for Structural Modifications of Pharmacies • Transfer of Refills Request by Patient • Modify Dosage Forms in Home Health Care Emergency kits • Pending Federal Regulations (FDAMA 1997) • High School or GED Required of Pharmacy Technicians • Pending Legislation Affecting the Practice of Pharmacy
May 27	**Board Meeting** • Board Sponsored Legislation • Legislation Introduced Affecting the Practice of Pharmacy • Regulations Update
July 28	**Board Meeting** • Personal Responsibility And Work Opportunity Reconciliation Act of 1996 • Board Sponsored Legislations (SB 2239) • 1998 Pending Legislation Affecting the Practice of Pharmacy • Regulation Update

1998 (CONTINUED)	
OCTOBER 28	**Public Meeting** ♦ Proposed 1999 Legislation ♦ Proposed 1999 Regulations
NOVEMBER 30	**Committee Meeting** ♦ Finalize List of Proposals for Board-Sponsored Legislation and Regulations for 1999. Proposals Considered: · Patient Compliance Programs · Pharmacy Law Examination for Non-Licensed Owners · Adjustment of Dosage Form · Proposed Changes to the Emergency Kit Regulations (CCR 1751.11) · Revoked Licensees Prohibited from Other Board Licensure · Point of Care Testing ♦ Proposals from the Public

1999	
JANUARY 20	**Committee Meeting** ♦ Adoption of California Code of Regulations Section 1793.6 Dealing with Pharmacy Technician Trainees
MARCH 18	**Committee Meeting** ♦ Review 1999 Introduced Legislation Affecting the Practice of Pharmacy and Recommend Board Positions
DECEMBER 14	**Committee Meeting** ♦ Proposed Legislation for 2000: ♦ Quality Assurance Program ♦ Ambulance Restocking ♦ CURES Spot Bill ♦ Omnibus Provisions ♦ Implementation of 1999 Legislation: ♦ SB 393 (Speier) ♦ AB 162 (Runner) ♦ CURES Task Force Meetings ♦ Internet Pharmacy Update

2000	
JANUARY 18	**Committee Meeting** ♦ Update on Board-Sponsored Legislation ♦ Regulations Proposed for 2000 ♦ Update on Pending regulations ♦ CURES Conference ♦ Legislation Introduced Affecting the Practice of Pharmacy
MARCH 24	**Committee Meeting** ♦ Regulation Update ♦ Review of 1999 Legislation ♦ Review of current Legislation
JUNE 16	**Committee Meeting** ♦ July Regulation Hearing on Citation and Fine ♦ Regulation Update ♦ Legislative Update ♦ Consideration of Current Legislation
SEPTEMBER 20	**Committee Meeting** ♦ Regulation Update ♦ Review of Draft Quality Assurance Regulation ♦ Legislative Update ♦ Review of Strategic Goals
OCTOBER 18	**Public Committee Meeting** ♦ Proposed Regulations for 2001 ♦ Proposed Legislation for 2001 ♦ Public Requests for Legislative and Regulatory Changes ♦ Open Comment

2001	
JANUARY 4	**Committee Meeting** ♦ Regulation Update ♦ Quality Assurance Program ♦ Changes to the Administrative Procedure Act ♦ Proposed 2001 Legislation

2001 (CONTINUED)	
APRIL 11	**Committee Meeting** ♦ Regulations Update ♦ Update on Board-Sponsored Legislation ♦ 2001 Legislation for Consideration
JULY 10	**Committee Meeting** ♦ Regulations Update ♦ Quality Assurance Program ♦ Update on Board-Sponsored Legislation ♦ Update on 2001 Legislation ♦ Draft Legislation on Sterile Compounding
SEPTEMBER 20	**Committee Meetings** ♦ Regulations Update ♦ Update on 2001 Legislation ♦ Bills for Consideration in the 2002 Legislative Session
OCTOBER 15	**Public Committee Meeting** ♦ Regulations Update ♦ Legislative Update ♦ Informational Hearing on Draft Regulation Proposals

2002	
JANUARY 8	**Committee Meeting** ♦ Regulations Update ♦ Legislative Proposals for Board Sponsorship ♦ SB 293 Update ♦ Proposed Rulemaking – Internet Dispensing and CMIA Citation and Fine Regulation
APRIL 11	**Committee Meeting** ♦ Regulations Update ♦ Legislation Update ♦ Legislation for Consideration ♦ Briefing for the Informational Hearing on Sterile Compounding Guidelines ♦ Fiscal Estimates for Pending Legislation
JUNE 28	**Committee Meeting** ♦ Regulations Update ♦ Legislation Update ♦ Legislation for Consideration

ENFORCEMENT COMMITTEE

GOAL: Exercise oversight on all pharmacy activities.

VISIONARY LEADERSHIP – SIGNIFICANT ACCOMPLISHMENTS – MAJOR CHANGES

COMMITTEE OVERVIEW

The Enforcement Committee oversees all enforcement activities of the board; these activities are essential for the board to meet its consumer protection mandate. Enforcement is a board priority both in terms of funding and staffing, and enforcement expenditures comprise about 70 percent of the board's $7.5 million annual budget.

The enforcement program uses a combination of education, communication, and enforcement sanctions to achieve compliance with federal and state pharmacy laws. Where voluntary compliance and education are not enough, the board inspects, mediates, admonishes, cites and fines, and pursues formal disciplinary actions.

Pharmacy laws are enacted to protect the public and the inspection process is an opportunity for a proactive approach to educate pharmacists about the legal requirements and standards of practice they are expected to meet. During an inspection, the inspector, who is also a licensed pharmacist, may provide information on patient consultation, pain management, quality assurance programs or advice on any other matter. Routine inspections help ensure ongoing voluntary compliance with pharmacy law by the board's licensees because the potential to be inspected at any time serves as a major deterrent to violating pharmacy law. Detect problems before they become major violations threatening public safety. Inspections also identify drug diversion practices, negligence, incompetence, and inappropriate record keeping practices.

The educational component of enforcement is also provided by the pharmacy self-assessment program, responses to inquiries to the board's office and staff, information displayed on the board's Website, and during the public meetings of the board and all committees. The board develops written materials specifically to educate licensees -- Compliance Policy Guides are developed to provide licensees with information about the board's interpretation of complex legal areas. The board assures the periodic printing of the *Pharmacy Lawbook*, and as funding permits, mails a *Pharmacy Lawbook* to all California pharmacies (typically every two years).

The board's newsletter *The Script* and *Health Notes* monographs provide direct information to licensees about board polices and items important to practitioners' compliance with laws. The self-assessment program requires all pharmacies to perform a periodic self-inspection of their facilities, aiding pharmacies' compliance with federal and state pharmacy laws. But where education is not enough, the board's inspectors investigate cases than can lead to citation and fine penalties, and to more severe sanctions such as license revocations or other discipline via formal action authorized by the Administrative Procedures Act.

Since the last sunset review, a number of substantial changes have altered the board's enforcement program and the board's policies for enforcing laws. The most notable changes are described below.

Committee and Team Meetings, and Structure

The Enforcement Committee meets quarterly with all 34 enforcement program staff. The board has 22 pharmacist-inspectors and additional complaint analysts who mediate consumer complaints. This is the only committee that meets with all program staff and these meetings are called "Enforcement Team" meetings. The quarterly meetings are essentially staff meetings and are not open to the public because investigative strategies are discussed. However, team-meeting summaries are provided to the board at each of its board meetings, and at least two Enforcement Committee meetings a year are public meetings. However, since July 2002, the Enforcement Committee has had three board members appointed as members so all meetings will be public in the future. All policy recommendations from the Enforcement Committee are referred to the board for action at the next regularly scheduled board meeting.

The Enforcement Committee began its team meetings in 1997. This was a crucial time because the board's enforcement program was initiating major changes to its organizational structure that affected all operations. These changes were necessary to manage the inspector workload statewide and to improve use of the board's inspectors to investigate violations that require the expertise of a pharmacist. It was also necessary to successfully assimilate the board's strategic plan into its enforcement operations.

During this time through the leadership of the Enforcement Committee, territory models of assigning work were eliminated and instead the board's inspectors were able to select and work on one of three teams: the Compliance Team, the Drug Diversion/Fraud Team and the Pharmacist Recovery Program (PRP) Monitoring Team.

- The Compliance Team investigates complaints involving prescription errors, Internet dispensing and unprofessional conduct and performs routine compliance inspections of all board-licensed facilities.

- The Drug Diversion/Fraud Team investigates alleged violations of pharmacy law involving drug diversion, excessive dispensing, corresponding responsibility, fraud, criminal convictions involving drug diversion/fraud, bid contract diversion and import/export activity. These are usually high priority and complex cases, and require tremendous board resources.

- The PRP/Probationer Monitoring Team monitors pharmacists on probation or who are in the board's Pharmacist Recovery Program. Through quarterly inspections and other reporting mechanisms, this team ensures a probationer's compliance with the terms and conditions of the probation. In addition, this team investigates allegations of a pharmacist's self-use of drugs.

A fourth team, the Complaint Mediation Team was also developed and staffed by complaint analysts who mediate consumer complaints, research criminal convictions, and perform in-house investigations of technical violations of pharmacy law -- work that does not require the knowledge of a pharmacist.

Beginning with the January 1999 team meeting, the Enforcement Committee established standard agenda topics that would be addressed at every meeting that were important to the board's staff and development of the team. Primarily these were inspector issues and quality improvement efforts. At subsequent meetings, each inspector team reported on the status of cases, significant accomplishments, completed training programs, and attendance at meetings. Management also provided reports of case status and closure statistics by team and individual, which display the status of pending complaints and investigations. Four years later, this same meeting format focuses on case management reports to ensure that the board's performance expectations for each team are being met.

In addition, the Enforcement Team discusses proposed or pending legislation and the implementation of new laws, reviews and proposes statutory and regulation changes, develops compliance policies and guidelines, proposes procedures for implementing new laws and educating licensees during the implementation phase, proposes strategic objectives and discusses investigative strategies. Since 1997, all recommendations for changes to the enforcement program are first considered by the Enforcement Committee and then forwarded to the board. The dates and the agenda topics for each Enforcement Team and Committee Meeting are charted at the end of this section.

CASE MANAGEMENT

In March 2000, the Bureau of State Audits initiated an investigation of the Board of Pharmacy under the provisions of the California Whistleblower Protection Act. The allegation was that the board had an excessive backlog of consumer complaints and was not doing its job to investigate all complaints.

In April 2001, the bureau issued its report that found that the board did not promptly resolve complaints. The report cited data regarding the board's program that was not current and at least one year old. The bureau reported that the board had a backlog of 770 complaints as of March 6, 2000. The bureau calculated that this was about half of the 1,552 open complaints.

When the Bureau of State Audits released its report, the board had dramatically reduced the number of complaints pending to only 393 complaints older than 181 days that had not been investigated or mediated. This reduction was accomplished during a time span where:

- complaints received by the board had increased (for example, from 1997/98 to 1999/00, the total number of annual complaints increased 49 percent from 873 to 1,298);
- there were substantial staff vacancies in inspector positions;
- eight new inspectors and one supervising inspector had been hired since July 2000; and
- new inspectors were undergoing the training required to function fully.

The Board of Pharmacy was very much aware of its pending backlog of complaints before the Bureau of State Audits initiated its review. In fact, the reason why there was a whistle blower complaint in the first place was that the Enforcement Committee reported on the status of these cases during public board meetings and reported on its efforts to reduce the backlog.

Beginning in 1999, the inspector teams reported on their current caseload at each Enforcement Team Meeting and efforts were initiated to focus staff on resolving the cases expeditiously. Not only did the organizational changes to the board's enforcement program add to the backlog, so did the high vacancy rate in inspector positions (at one time, there were 10 positions vacant or about 50 percent of these positions). Therefore, all routine inspections were suspended and inspectors were redirected solely to the resolution of consumer complaints and investigations over one year old. Additionally, a specialized mediation team of non-inspector analysts focused on the resolution of consumer complaints although inspectors were also trained on the mediation process as well.

Vacancies in Pharmacy Inspector Positions

The Bureau of State Audits reported that if all the inspector positions had been filled in the past, there would have been no backlog of consumer complaints. While this was a significant point, the report failed to recognize the extraordinary activities undertaken by the board since 1994 to correct what would ultimately result in the high vacancy rate of inspectors – a significant salary disparity to recruit quality inspectors for the board's inspector positions. Board action to obtain increased salaries for its inspectors began in 1994, before there was a significant vacancy problem. Specifically the board undertook a number of activities that included:

- targeting the need for higher inspector compensation in its 1996 Sunset Report as key component necessary for board operational efficiency (Volume 1, page 128);
- developing reclassification proposals and salary realignments for the inspector series (denied by the Department of Personnel Administration);
- sponsoring legislation to create statutory links of inspector salaries with the salaries paid to UC pharmacists [SB 2239 (1998) and SB 1308 (1999)]; both of which were opposed by the administrations of two governors and were amended out of the bills late in the respective session;
- pursuing numerous high-level discussions with administration officials and written requests to the Governor to recognize inspectors as under-compensated workers (denied by Governor Wilson);
- securing continuous application processes to aid in inspector recruitment (previously competitive civil service examinations were given only once every two years);
- publishing articles about inspector positions available in the board's quarterly newsletter that is mailed to all California licensed pharmacists (for recruitment); and
- hiring all inspectors from the private sector at the top step of the inspector salary range (which requires specific approval from the Department of Personnel Administration).

These efforts paid off in 1999, during the collective bargaining process. Inspectors were given a special salary alignment of 10 percent. This augmentation, coupled with two 4 percent raises provided to all-state employees over a one-year period, reduced the salary inequity. The higher salary for inspectors was available for recruitment purposes beginning with the April 2000 application process and was featured in another board newsletter article mailed to all California pharmacists. It was from this applicant pool that at long last the board was successful in drawing high quality pharmacists, and as of January 2002, all 19.5 inspector positions had been filled.

Chief of Enforcement

In 2001/02, the Board of Pharmacy submitted a budget change proposal to add a manager as chief of enforcement and increase the number of supervising inspectors from two to four. The Department of Finance denied nearly the entire request but approved funding of $6,000 to upgrade an existing inspector position to supervising inspector. Then through a spring finance letter to implement the provisions of SB 293 (to establish a specialized compounding pharmacy permit that requires annual inspections by the board) the Department of Finance approved another supervising inspector position for the 2002/03 fiscal year.

While it is noteworthy that beginning July 1, 2002, the Board of Pharmacy will have sufficient supervisors to manage its field inspectors at a ratio of 1:5, the board still needs a chief of enforcement to manage its complex and highly visible enforcement program.

The chief of enforcement would provide for a fully integrated and consistent program, and would consolidate, interpret, and develop policies for enforcing California pharmacy law. The position would serve as the liaison with the Attorney General's Office and ensure for example, that:

- stipulations are consistent with board guidelines for the type of violation involved,
- interim suspension orders are pursued consistently and immediately when dangerous conditions exist and board expertise is available to pursue these orders,
- decisions from administrative law judges are evaluated for consistency with board guidelines, and
- feedback is provided to the executive officer and enforcement staff regarding what went right and/or wrong on formal disciplinary cases.

The chief would also work closely with the four supervising inspectors to assure consistent enforcement practices, interpretations of law and administration of pharmacy law by all 20 inspectors.

The chief would provide considerable assistance to the board and executive management in the administration of the board's total program (also involving staff from licensing, legislation, and communications), and provide a unified and concentrated head for the enforcement program.

Another duty would be the development or procurement of specialized training programs to upgrade the skills of all inspectors (e.g., aseptic compounding, nuclear pharmacy practices, quality assurance programs, root cause analyses, and the use of computer software now found in pharmacies). This is necessary to keep inspectors' knowledge of pharmacy practice up-to-date. The board will continue to pursue creation of this position in the future.

Controlled Substances Utilization Review and Evaluation System (CURES)

Since 1940, outpatient prescriptions for Schedule II controlled substances are required to be written on a three-part, state-issued form known as the "triplicate." Prescribers must order the preprinted triplicates from the Department of Justice. Schedule II prescriptions for patients who are terminally ill or who are admitted to a hospital are exempt from the triplicate requirement. Three copies are required: the prescriber retains one copy, the pharmacy retains one copy, and the original is forwarded to the Department of Justice by the dispensing pharmacy.

The purpose of the triplicate program is to reduce the diversion of Schedule II controlled substances from the legitimate pharmaceutical market to the illicit market. The program attempts to achieve this end by restricting the availability of the triplicate forms and monitoring the dispensing of these drugs by analyzing the returned forms. While this is the goal, the Department of Justice has been unable to accurately monitor dispensing because fewer than 1 percent of the total triplicate prescriptions dispensed were manually keyed into the computerized database of the department.

In 1998, through a $1 million augmentation, the Board of Pharmacy funded CURES, which was established by AB 3042 (Takasugi, Chapter 738, Statutes of 1996) as a three-year pilot project. CURES tracks outpatient prescriptions dispensed in California for all Schedule II controlled drugs. Each month, pharmacies transfer computer files detailing the Schedule II prescriptions dispensed by the pharmacy. This data is compiled into a statewide database, which can be queried by law enforcement, regulators, and qualified researchers. From the program's inception in May 1998 to June 30, 2002, the CURES program has processed over 10 million prescriptions. In 1999, the Legislature approved a sunset extension for CURES (sponsored by the Board of Pharmacy) until December 1, 2003.

To implement CURES, the board passed a regulation that mandates pharmacies to participate in the program. To encourage pharmacies to participate in the program by July 18, 1998, the board granted a one-time license renewal rebate of $75 per pharmacy. The board outsourced the collection and maintenance of the triplicate prescription data to two vendors at a total cost of over $200,000 per year. Thus, the $1 million augmentation carried the program through December 31, 2001.

The board did not receive additional staff or resources to implement CURES. A pharmacy is checked for compliance during a routine inspection. In addition, inspectors use the CURES data for inspections to ensure appropriate dispensing of Schedule II controlled substances.

This year, the Board of Pharmacy is sponsoring AB 2655 (Mathews), which would extend the sunset provision for CURES until December 2008, and would allow health practitioners to access the prescription data for their patients. Meanwhile, the board will continue to fund the program (along with other health licensing boards) with the board's share at $70,000 per year.

Over the next year, the board's goal is use the CURES data more proactively to identify suspicious dispensing of controlled substances. Also, the board will work with the Bureau of Narcotics Enforcement and other regulatory agencies to coordinate efforts to educate

practitioners (through access to the data) about patients who are receiving Schedule II medications from multiple prescribers or pharmacies.

Quality Assurance Program to Prevent Prescription Errors

In October 2000, Governor Davis signed legislation (SB 1339, Figueroa, Chapter 677) requiring all pharmacies to develop quality assurance programs to study and evaluate prescription errors to prevent recurrence of such errors. In 2001, the board promulgated regulations to establish the parameters for the quality assurance programs, which became effective January 2002.

In July 2002, the board received the Council on Licensure, Enforcement, and Regulation's (or CLEAR's) Program Award for this major consumer protection initiative aimed at preventing prescription errors.

The board's goal for quality assurance programs is to reduce the frequency of medication errors through the systematic study of the errors. Such study will provide pharmacists with the knowledge to improve pharmacy processes and enhance existing procedures to reduce the incidence of medication errors.

The Board of Pharmacy sponsored this legislation out of concern with the growing body of evidence documenting the threat of medication errors to patient health. Medication errors are the most frequent consumer complaint received by the board, and the board believes that systems and process analysis is the most effective means to reduce the frequency and severity of medication errors.

California is the first state in the nation to require quality assurance programs for pharmacies. This proposal was a strategic objective of the Enforcement Committee since 1999.

Pharmacy Self-Assessment

In January 1999, the Board of Pharmacy implemented its self-assessment forms for pharmacies. The forms must be completed by the pharmacist-in-charge (PIC) every two years and when there has been a change in the PIC. The purpose of the self-assessment form is to educate the PIC and pharmacists on the requirements of pharmacy law, seek voluntary compliance, and remove the guesswork from what the board uses as criteria during an inspection.

Expanded Authority for Citation and Fines

In July 2001, regulations to expand the scope of the board's citation and fine program became effective to allow the board to cite and fine for any violation of pharmacy law. Prior to this change, the board issued citations and fines for failure to provide patient consultation, unlicensed activity, and continuing education violations.

The Board of Pharmacy pursued this regulation to provide it with intermediate sanctions between informal admonition and formal disciplinary action. Virtually all pharmacy and pharmacist violations are issued by a two board member Citation and Fine Committee appointed by the board president. All other citations and fines (for non-pharmacy entities and individuals) may be issued by the board's executive officer.

Routine Compliance Inspections

The practice of pharmacy is complex and highly regulated. It is the only profession where the practitioner is regulated (the pharmacist), the practice site is regulated (the pharmacy) and product is regulated (the prescription drug and devices that are dispensed). Over the years, efforts to protect the public have been pursued through proactive routine inspections by board inspectors to ensure compliance with the myriad of state and federal laws. However, there is no mandate in pharmacy law that these unannounced inspections be performed, although the board believes such inspections can correct minor problems before they become major violations and are important to compliance and education of the board licensees.

Because of limited resources, the Board of Pharmacy's policy is to inspect a pharmacy at least every three years. In addition to routine inspections, pharmacies are also inspected as part of a complaint investigation. However, due to vacancies and investigative priorities during the late 1990s, the board was not able to continue inspections and in 2000, the board suspended all inspections until it was able to reduce its backlog of complaints/investigations and hire more pharmacist-inspectors. Routine inspections resumed July 1, 2001, once the board filled its vacant inspector positions.

The Compliance Team is responsible for these unannounced inspections. Each pharmacist-inspector is assigned specific pharmacies to inspect and must complete at least 32 inspections per month. The supervising inspector may adjust the number of inspections assigned to an inspector depending on the fluctuation of that inspector's complaint/investigation workload. For fiscal year 2001/02, the Board of Pharmacy completed 2,624 routine inspections, which resulted in the opening of 104 investigations and the ordering of over 2,000 separate corrections of pharmacy law.

Violations of the Confidentiality of Medical Information Privacy Act

In 2002, the Board of Pharmacy adopted a regulation to further expand its citation and fine authority to include violations of the Confidentiality of Medical Information Privacy Act. Senate Bill 19 (Figueroa, Chapter 526, Statutes of 1999) granted the board the authority to issue a citation and fine up to $2,500 per violation for negligent disclosure of confidential patient information in violation of the act. The board may issue a fine of up to $250,000 per violation for a knowing or willful violation for personal gain in violation of the act. The board is the first agency in the department to pursue this authority.

Violations of Internet Dispensing of Prescription Medications without a Valid Prescription

In May 2002, the board issued an $88 million fine to a California pharmacy and the two pharmacists who were dispensing prescription drugs without a valid prescription to over 3,500 California patients. Patients completed an online questionnaire instead of receiving a physical examination by their physicians. The patients ordered prescription drugs from a Website by providing only such information as height, weight, gender, and their credit card numbers. From this very limited information, a physician, not licensed in California, issued a prescription without examining the patient or having any knowledge about the patient's health or pre-existing conditions, in violation of California law. The prescriptions were then faxed to the pharmacy

for processing and mailed to California residents. Most of the prescription drug orders were "lifestyle" drugs. "Lifestyle" drugs are typically used for male impotence, balding, dieting and skin care. Patients paid substantially more for these drugs than if obtained through legal medical care routes and potentially risked their health since no medical assessment was done.

The authority to issue the fine came from legislation authored by Senator Speier (SB 1828, Chapter 681), which became law in January 2001. The bill provides the board with the authority to pursue these fines via action with the Attorney General's Office.

The Board of Pharmacy also adopted a regulation in January 2002 to expand its citation and fine authority to $25,000 per violation for dispensing a prescription or device on the Internet without a valid prescription or a good faith examination by a physician. The regulation is currently awaiting approval from the administration before filing with the Office of Administrative Law.

ENFORCEMENT TOOLS TO ENHANCE PUBLIC PROTECTION EFFORTS

The board is constantly evaluating and pursuing new legislative means to enhance its public protection efforts. For example, the Board of Pharmacy also sponsored provisions enabling it to suspend a license under specific circumstances:

- ***Automatic Suspension*** – a licensee is automatically suspended from practice while incarcerated following a felony conviction. The intent is for the suspension to continue as long as the incarceration, but the provision does not provide the final administrative resolution to be imposed for the conviction.

- ***Summary Suspension*** - a summary suspension of a license is authorized for a conviction of a felony committed in the course of the business or practice for which the board issues a license, or is committed in a manner that a client, customer, or patient of the licensee was a victim. This section also provides for the summary suspension for a crime where an element of the offense involves either the specific intent to deceive, defraud, steal or make a false statement or involves the illegal sale or possession for sale of or trafficking in any controlled substance. Under this provision, the board could summarily suspend a licensee who is not incarcerated or is incarcerated for a conviction of a crime.
- ***Interim Suspension*** – an interim suspension of a license is authorized when the board determines that a felony conviction is substantially related to the qualifications, functions or duties of the licensee.
- ***Cease and Desist Order*** - SB 293 (Torlakson, Chapter 827, Statutes of 2001) that became effective in January 2002, gives the executive officer the authority to issue an order to a pharmacy to immediately cease and desist compounding injectable sterile drug products. This order must be based on information obtained during an inspection or investigation by the board and the activity of the pharmacy poses an immediate threat to the public health or safety. The cease and desist order is only in effect for 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

In addition to temporary restraining orders and interim suspension orders, the board uses other means to ensure public protection during the sometimes time-consuming administrative discipline process. For example, Penal Code section 23 (or PC 23) is used to obtain suspension of a pharmacist's license through the criminal courts until the board can take administrative action. Under PC 23, the criminal courts can impose a summary suspension of a pharmacist's license during the criminal proceedings. These are cases where the board is aware of a criminal arrest and through the Attorney General's Office, requests during the arraignment that the pharmacist's license be suspended pending the resolution of the administrative case.

Enforcement Committee and Team Meetings

1997 to Present

1997	
August 25	**Initial Enforcement Committee Meeting** with Executive Management, Supervising Inspector and Enforcement Coordinator

1998	
January 7	**Enforcement Team Meeting** • Board's Strategic Plan • Discussion on Implementation (Driving/Restraining Forces) • Team Charters, Assessments and Job Descriptions
April 2	• Organizational Improvement Workshop for Inspectors Facilitated by Outside Consultant • Identification of Issues and Training Essential to Organizational Improvement
April 29	**Enforcement Committee Workshop** • Inspector Quality Improvement Efforts • Improvement to Inspection and Enforcement Process
June 24	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts • Proposed Inspector Team Concept • Reduction of Medication Errors
July 29	**Public Enforcement Committee Meeting** • Enforcement Committee Overview & Update – Introduction of New Inspector Teams • Overview of Board's Enforcement Process • Medication Errors – Scope of the Problem – Proposed Solutions • Implementation of Self-Assessment Program • Public Comment on Other Enforcement Issues
October 8	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts • Proposed Team Concepts/Inspector Team Selection • Implementation of Self-Assessment Program

1999	

JANUARY 7	**Enforcement Team Meeting**
	• Inspector Issues
	• Quality Improvement Efforts – Case Management
	• Medication Errors
	• FDA/NABP Evaluation of Written Prescriptions Drug Information Study
	• Implementation of Self-Assessment Program
	• Implementation of New Legislation
	  ▪ Triplicate Exemption for Terminally Ill Patients
	  ▪ Implementation of CURES

MARCH 9	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Medication Errors • Proposed Regulation for Quality Assurance Programs • MOU on Interstate Distribution of Compounded Drugs • NCC/SCC Meetings – Case Referrals • Strategic Plan Review & Update
MAY 10	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Report on Pending Legislation • Follow-up on Miscellaneous Issues: Medication Errors, Compliance Committee Guidelines for Meetings, CURES, Self-Assessment for Pharmacies, Terminally Ill Exemption
MAY 19	**Public Enforcement Committee Meeting** • Interpretation and Application of CCR section 1707.3 requiring a pharmacist's review of a patient's drug therapy and medication record before each prescription is delivered • Should the board require pharmacists to input a prescription into the computer as part of drug utilization review and as a means to prevent prescription errors? • Other enforcement issues that the public wanted to comment on

1999 (CONTINUED)	
JUNE 30	**Enforcement Team Meeting** ♦ Inspector Issues ♦ Quality Improvement Efforts – Case Management ♦ Prescription Errors – Proposed Quality Assurance Regulation ♦ NCC/SCC Meeting Guidelines ♦ Request to Amend CCR 1716 Regarding the Dispensing of Cyclosporine Drugs ♦ Miscellaneous Issues ♦ Strategic Objectives for 1999/00
SEPTEMBER 28	**Enforcement Team Meeting** ♦ Inspector Issues ♦ Quality Improvement Efforts – Case Management ♦ Update on 1999 Legislative Session ♦ Psychological Evaluation Procedures for Probationers ♦ Healthcare Integrity and Protection Data Bank ♦ Prescription Error Complaints ♦ Expansion of Cite and Fine Authority ♦ Compliance Committee Process – Proposed Regulations ♦ General Correspondence regarding Enforcement Program
DECEMBER 17	**Enforcement Team Meeting** ♦ Inspector Issues ♦ Quality Improvement Efforts – Case Management ♦ Proposed Newsletter Articles – Q & A ♦ New Legislation Effective January 2000 ♦ Update on Pending Regulations · Expansion of Cite and Fine Authority · Quality Review Programs · Pharmacy Operations During Temporary Absence of a Pharmacist · Disciplinary Guidelines · Revisions of Self-Assessment Regulation ♦ General Discussion and Policy Direction on the Implementation and Enforcement of Emergency Regulation – Pharmacy Operation During the Temporary Absence of a Pharmacist ♦ CURES Workgroup and Proposed Prescription Controlled Substance Abuse Prevention Task Force

2000	
MARCH 21	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Proposed Cite and Fine Regulations • Proposed Legislation for 2000 • Strategic Planning for 2000/01 – Environmental Scan on Compliance Policy Issues and Direction • Hospital – Inpatient/Outpatient/Satellite Pharmacies • Methadone Dispensing • Nurse Practitioners/Physician Assistants • Electronic Transfer of Refill Prescriptions
JUNE 20	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Proposed Changes to the Disciplinary Guidelines • Legislation Update • Cite and Fine Regulations • Request to Modify CCR 1717.3 • Review of Strategic Objectives for 2000/01 • Implementation of New Regulations • Evidence Procedures
JULY 25	**Public Enforcement Committee Meeting** • Expiration Date Proposal • Patient Confidentiality Issues – Presentation of Enforcement Examples • Prescriber Dispensing – Legal Interpretation of Pharmacy Law • Overview of Enforcement Process • Self-Assessment Form – Request for suggested revisions to the form and law changes for future consideration
SEPTEMBER 14	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Report on July Enforcement Committee Meeting • Legislation/Regulation Update • Proposed Procedures for Routine Compliance Inspection Program • Delegation of Authority to Board President for Petitions to Compel Psychiatric Evaluations. • Review of Strategic Objectives for 2000/01 • Guidelines for Discipline of Technicians • Compliance with SB 393 – Medi-Cal Discount for Medicare Patients • Price Quotes for Medicare Patients • Suggested Revisions to Self-Assessment Forms

2000 (CONTINUED)	
DECEMBER 12	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Implementation of Routine Compliance • Inspection Program • Update on New Laws • Proposed Regulations on Quality Assurance Programs • Proposed Regulations to Cite and Fine for Violations of Internet Dispensing and Confidentiality of Medical Information Act • Implementation of Waiver for Off-Site Storage of Records • Review of Comments for Proposed Amendments to CCR 1717.3

2001	

MARCH 12	**Public Enforcement Committee Meeting**
	• Expiration Date on Labels – Guidelines for Enforcement
	• Prescriber Dispensing – Legal Interpretation of Pharmacy Law
	• Responsibility of the Pharmacist-In-Charge
	• Proposals to Change the Enforcement Process
	  - Provide a written statement to licensee when it pursues a disciplinary action that addresses "Factors to be Considered in Determining Penalties"
	  - Establish a board committee to determine level of disciplinary action
	  - Inspection and investigation reports should contain information of mitigation provided by the licensee
	• Request to Amend 1709.1 to Allow a Pharmacist-in-Charge to be Responsible for More than One Pharmacy
	• Request to Amend 1793.3 to Eliminate the Clerk-Typist Ratio and Expand the Duties of the Clerk-Typist
	• Public Comment on other Issues

MARCH 12	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Implementation of Routine Compliance Inspection Program • NCC/SCC Process • Discussion of Enforcement Issues from Enforcement Committee Public Meeting • Proposed Strategic Objectives for 2001/02

2001 (CONTINUED)	
JUNE 27	**Enforcement Team Meeting** • Inspector Issues • Quality Improvement Efforts – Case Management • Request to Amend CCR 1717.3 for Hospital Impatient Pharmacy • NCC/SCC Process – Implementation of Cite and Fine Regulation and Quality Assurance Program • Discussion of Proposals to Improve Disciplinary Process • Review of Strategic Objectives for 2001/02 – Identify activities for Implementation
SEPTEMBER 25	**Public Enforcement Committee Meeting** • Prescriber Dispensing – Legal Interpretation of Pharmacy Law • Pharmacist Recovery Program – Suggested Opportunities for Improvement • Proposed Procedures for Implementation of the Cite and Fine Regulations • Proposed Procedures for Inspection and Investigation/Mediation of Prescription Error Complaints Implementation of Quality Assurance Regulation • Proposed Complaint Disclosure Policy for the Department of Consumer Affairs – Current Board Complaint Disclosure Policy • Questions and Answers for Board Inspectors on Pharmacy Law • Questions and Answers on Specific Closed Administrative Cases
SEPTEMBER 25	**Enforcement Team Meeting** • Quality Improvement Efforts – Case Management • Status Report on Routine Compliance Inspection Program • Suggested Opportunities for Improvement to the Pharmacists Recovery Program • NCC/SCC Procedures – Implementation of Cite and fine Regulation – Quality Assurance Program Regulation • Compliance Guide on Prescriber Dispensing • Proposed DCA Complaint Disclosure Policy and Board's Complaint Disclosure Policy
DECEMBER 4	**Enforcement Team Meeting** • Quality Improvement Efforts – Case Management • Routine Compliance Inspection Program • New Pharmacy Laws • Pharmacist-in-Charge Guidelines • Implementation of Cite and Fine Regulations • Discussion of Implementation Issues • Implementation of Quality Assurance Regulation

2002	

MARCH 12	**Public Enforcement Committee Meeting**
	• Proposed Cite and Fine Committee and Process
	• Pharmacist-In-Charge Expectations
	• Quality Assurance Regulation
	• Remote Dispensing by a Pharmacist from the Enforcement Perspective
	• Review of CCR 1715.6
	• Clarification of Pharmacy Law Interpretation
	  - Technician Badges
	  - Technician Ratios
	  - Corresponding Responsibility
	  - Prescription Vial Return to Stock
	  - Requirement for Counseling Area
	  - Access to Pharmacy Records Outside a Pharmacy
	• Proposed Strategic Objectives for 02/03
	• Proposed DCA Complaint Disclosure Policy
	• Internet Pharmacy Enforcement

MARCH 12	**Enforcement Team Meeting** • Quality Improvement Efforts – Case Management • Discussion of Enforcement Committee Topics • Process for Petitions for Reconsideration • Proposed Strategic Objectives for 02/03
JULY 3	**Public Enforcement Committee Meeting** • Identity of Where Pharmacy Practice has Changed, But Pharmacy Law Has Not • Proposed Restitution for Consumer Harmed by Prescription Errors
JULY 3	**Enforcement Team Meeting** • Quality Improvement Issues – Case Management • Discussion of Enforcement Committee Topics • Revised Goal Statement for 2002/03 • Compliance Guidelines – Electronic Signatures • Discussion on Quality Assurance Regulation • Discussion on Citation and Fine Process • New FDA Compounding Guidelines • Revision of Enforcement Committee Strategic Goal

Blank Intentionally

Organizational Development Committee

Goal: Ensure the achievement of the board's mission and goals.

VISIONARY LEADERSHIP - SIGNIFICANT ACCOMPLISHMENTS – MAJOR CHANGES

Strategic Planning

The California State Board of Pharmacy attributes its organizational success to strategic management and planning. Over the years, the board has been able to integrate into its strategic planning processes, budgeting, program implementation, performance monitoring and reporting and program evaluation as well as tracking essential business functions. Because the pharmacy profession is dynamic and rapidly evolving, the board's strategic plan is a working document that is both visionary and realistic. It anticipates the future that is both desirable and achievable. It provides a structure to manage the future, facilitates communication and participation, accommodates divergent interests and values, and fosters practical decision-making and successful implementation.

The strategic plan reflects the board's basic strategies for continuing to meet is mission while working to achieve its vision. The board uses its strategic plan to determine its priorities and allocate resources. Board meetings are agendized using the strategic plan's five-committee structure. Work on current and emerging issues is assigned to the respective committee for review.

In 1994, the board adopted its first strategic plan. The board worked with a facilitator and the planning session was done during an open board meeting, which provided for input from the board's stakeholders. While the plan was visionary and reflected a future that was desirable, it did not provide for practical decision-making and follow through necessary for a regulatory agency mandated to perform a number of ongoing activities. The plan contained eight goal areas, but no organizational structure for implementation, follow-through and measurement. The most significant outcome of the initial plan was the strategy for the board's successful public education and consumer outreach program.

In 1997, the board comprehensively revised and restructured its plan. A facilitator again guided the strategic planning process in a public meeting, and this time the plan more accurately reflected the board's visionary leadership in relation to its public protection mandates and regulatory responsibilities. One of the most meaningful changes was the development of a committee structure to correspond to the board's mission-related goals and performance measures for these goal areas.

In 1998, the most significant change to the board's strategic plan was the process. That year, board staff through the leadership of a specialized "Transition Monitoring Team" (TMT) performed the environment scan. The TMT consisted of nine staff representing inspectors, analysts, and clerical employees, who were elected by staff. The TMT facilitated the environmental scan with staff and provided the results of this environmental scan to the board during the strategic planning session. The important participation of the TMT members and staff in the strategic planning process was significant. The board's strategic plan was developed from the bottom of the organizational structure (staff) to the top (board), instead of from the top to the bottom (from the board to staff). This planning process produced a more realistic strategic plan and a better understanding by the board and staff of the process and plan, which is important for successful implementation.

From 1999-2001, the board updated its strategic plan annually. This was done during open board meetings, where public participation was also encouraged.

The board's strategic plan is integrated into the board's day-to-day operations through the committee process. Each committee oversees its goal areas and is responsible for implementation. Each committee meets before each board meeting to discuss its activities and issues. At the board meeting, the committee reports on the issues and makes recommendations for board action. Each committee issues a written quarterly status report on the implementation of the strategic and ongoing objectives for each goal area.

Each year the board reviews and revises its strategic plan. The process starts with the staff who perform an environmental scan and forward the scan to the board for inclusion in the plan. Then through each of the committees, staff propose strategic objectives for the upcoming year. Each year the strategic objectives are revised as well as the performance measures and indicators.

In 2002, the board initiated a substantial revision to the strategic plan, reflecting the new composition of the board and the guidance of a new facilitator. A new vision and purpose were refined from the prior plans. But the overall activities of the committees to secure the goals will remain, as will a quarterly reporting of each committee's progress in reaching its strategic goals.

BUDGET MANAGEMENT

An integral function of the Organizational Development Committee is to oversee the board's budget and assure that adequate resources exist to perform mandated board business. It is necessary that the board's financial resources be managed to ensure fiscal viability and program integrity. At each meeting, the committee reviews budget forecasts and expenditure reports. These reports are also shared with the board at every board meeting.

Since the last sunset review, the board's staff and annual expenditures have increased from $5.2 million in 1996/97 to $7.5 million in 2002/03 – a 44 percent increase.

Also since the last sunset review, the board was able to reduce fees to their statutory minimum (effective July 1, 1999) as repayment of the 1991/92 General Fund transfer occurred. (The board had increased fees to their statutory maximum in July 1995 because the transfer had so depleted the board's reserve.) A growing reserve in the board's fund in the late 1990s made this fee reduction possible. As such the board sought to reduce the size of its reserve; revenues are currently $2 million less than annual expenditures intentionally as a means to reduce the size of the board's reserve. The board is directed by the Business and Professions Code to maintain a one-year reserve in its fund.

However, the transfer of $6 million from the board's reserve for the state's 2002/03 budget greatly depleted the board's reserve. A future increase in the board's fees will be needed to bring the board's revenue back in line with its expenditures in another year unless the board substantially reduces expenses in 2003/04 or receives repayment of the loan early in the next fiscal year (July 2003). Without repayment of the loan early in 2003/04 or unless substantial program cuts are made, the board will need to increase fees to their statutory limit, and eventually will need to seek an increase in the statutory maximum.

Over the years, the board has aggressively sought program enhancements and expansions through the budget change proposal process, which is required to increase the board's expenditure authority or add new staff positions. Although not many of the budget augmentation requests were approved, or when approved were approved at reduced levels, the board has nevertheless added staff and resources important in the board's productivity and visibility in each of the five strategic management committees' activities. *(see Part 1, Budget and Staff for more information.)*

STAFF DEVELOPMENT

The board appreciates and supports its staff, and development of staff is viewed as an essential function. Since the last sunset review, the board has instituted quarterly staff meetings with all staff to attain team building, integrate the board's strategic plan throughout the board and to share necessary information. This is essential for the board to continue to change and meet the challenges of regulating pharmacy professionals and facilities.

The formation of the Transition Management Team (TMT) in 1998 was to provide an alternative means for staff to deal with the discomfort caused by dramatic change, and instead build a stronger organization through staff development and participation in the change process. Recommended by consultants who advocate change management, the TMT provided a confidential means for staff to complain or approach management with concerns. Over a one-year period and through an aggressive training program provided to all staff by board management, staff voted to rename and reorganize the TMT into The Communications Team (TCT) with a focus on strengthening communication throughout the board. This was a significant achievement and reflection of the significant progress in both staff and organizational development. Since 1999, the TCT has hosted and organized all quarterly staff meetings, and works on team building. It also still serves as a confidential source of bringing problems to management's attention. Staff membership is now six members, each of whom is elected by all staff.

Staff is encouraged to identify and attend training that will strengthen and develop their skills. Much of the board's work is accomplished in team environments, and cross training is an important means through which the board completes work in light of vacancies, absences, and workload surges. Many staff are promoted within the board once they are ready for more complex assignments. Of the 52 staff currently employed by the board, 31 have been with the board more than three years (61 percent) and 20 of these staff with the board more than five years (39 percent).

OTHER MAJOR PROJECTS

The board developed a *Board Member Procedure Manual* to advise new and ongoing board members of board policies and state policies so that they can better carry out their duties without conflict.

Since the last sunset review, the committee has also coordinated the development of the board's Operational Recovery Plan, Business Continuity Plan and a fee audit; undertaken Y2K compliance issues and expanded the board's Sacramento headquarters office into much needed larger space; and installed a new, automated phone system.

Organizational Development Committee Meetings

1997 to Present

1997	
January 22	**Board Meeting** • The Administration's Strategic Plan Requirements and Need for Board to Update Strategic Plan • Sunset Review of the Board by the Legislature • Budget and Personnel Update • Inspector Salary Realignment and Reorganization • Use of Credit Cards for Renewal and Application Fees • Self Audit of Board Operations and Fees Planned • Bureau of State Audits Review of Board Revenue Collection and Disbursement Practices Scheduled
March 19 & 21	**Board Meeting** • Evaluation of the Executive Officer • Joint Legislative Sunset Review Committee's Recommendations for the Board of Pharmacy • Board Wins National Association of Boards of Pharmacy's Fred T. Mahaffey Award • Budget and Personnel Update • Audit of Board Operations and Fees Planned • Bureau of State Audits Reviews, Board Revenue Collection and Disbursement Practices Underway • Inspector Workshop Planned for August 1997 • Strategic Plan Revision Conducted
May 17	**Board Meeting** • Budget Report and Personnel Update • Contracting with the Department's Division of Investigation to Conduct Criminal Investigations • Auditor Selected to Perform Audit of Board Fees • Bureau of State Audits Review of Board Revenue Collection and Disbursement Practices Continues • Acceptance of Credit Cards by Board for Payment of Fees • Status Report on Automation Projects • Draft Reference Manual for Board Members Released • Department to Develop Requirements for Checking Immigration Status of Applicants • Future Board Meeting Dates for 1998
July 23 & 25	**Board Meeting** • Strategic Planning Revision Continues • Department Director Berte Advises Board She Will Initiate an Investigation of Anonymous Staff Complaints Sent to Board Members • Reference Manual for Board Members Shelved • Personnel Update and Budget Report • Bureau of State Audits Reviews, Board Revenue Collection and Disbursement Practices Completed

1997 (CONTINUED)	
SEPTEMBER 23	**Board Meeting** • Budget Report and Personnel Update • Y2K Conversion of Consumer Affairs Computer System (CAS) • Integrated Consumer Protection System Proposed by Department to Replace Existing Computer CAS System • Contract with Private Firm to Update and Publish Pharmacy Lawbook Update on Audit of Board Fees

1998	
JANUARY 21	**Board Meeting** • Board Member Training: Effective Decision Making, provided by the California Society of Health System Pharmacists • Budget and Personnel Update • Automation Update, including Integrated Consumer Protection System under Development by the Department of Consumer Affairs • Revision, Publication and Distribution of Pharmacy Lawbook to California Pharmacies • Results of Department's Investigation of Anonymous Complaints Provided to Board (Closed Session)
MARCH 19, 20	**Board Meeting** • Budget and Personnel Update • Staff Development • Automation Update • Board Meeting Dates for 1999 • Strategic Planning for 1998/99 • Discussion of Formation of a Staff Transition Monitoring Team to deal with the issues and communication problems that accompany organizational change
MAY 28	**Board Meeting** • Action Plan Update • The Staff Transition Monitoring Team Formed and Report to Board • Budget and Personnel Update • Staff Development • Automation Update • Clarification of Public Meetings Act • Annual Evaluation of Executive Officer
JULY 28	**Board Meeting** • Action Plan Update • Budget and Personnel Update • Continuous Application Process for Inspector Classification Established • Transition Monitoring Team Report • Automation Report

1998 (CONTINUED)	
OCTOBER 29	**Board Meeting** • Budget and Personnel Update, including Inspector Salary Upgrade • Need to Reduce Board Fees • Staff Development • Transition Monitoring Team Report • Automation Report

1999	
JANUARY 21	**Board Meeting** • Personnel and Budget Update • The Transition Monitoring Team Report • Update on the Board's Action Plan • Y2K Update/Automation Report • Presentation of Fee Audit Report
MARCH 25	**Board Meeting** • Personnel and Budget Update • The Transition Monitoring Team (TMT) Report and Conversion of the TMT into The Communications Team • Update on Board's Action Plan • Y2K Update/Automation Report
MAY 19	**Board Meeting** • Adoption of Strategic Plan for 1999/00 • Budget and Personnel Update • The Communications Team Report • Y2K Update/Automation Report
JULY 28	**Board Meeting** • Budget and Personnel Update • Y2K Update/Automation Report • The Communications Team Report
AUGUST 31	**First Formal Meeting of Organizational Development Committee** • Strategic Goals and Action Plan • Policy and Procedure Manual for Board Members • Required Ethics Training for Board Members • Fee Audit Report • Budget and Personnel Update • Y2K Update

2000	
JANUARY 5	**Committee Meeting** • Preparation for Strategic Plan Revision • Budget and Personnel Update • Update on Pending Projects: • Policy and Procedure Manual for Board Members • Required Ethics Training Manual for Board Members • Fee Audit Report • Pharmacy Lawbook Distribution • Y2K Update • Development of Board Website
MARCH 20	**Committee Meeting** • Preparation for Strategic Plan Revision • Budget and Personnel Update • Update on Projects: • Policy and Procedure Manual for Board Members • Fee Audit Report • New Phone System
APRIL 12	**Public Board Meeting** • Strategic Planning for 2001/02
JUNE 15	**Committee Meeting** • Strategic Goals for Committee for 2000/01 • Plans for Adoption of Board's Strategic Plan • Budget and Personnel Update – including BCPs for 2001/02 • Selection of Board Meeting Dates for 2001 • Revisions to Policy and Procedure Manual for Board Members • Reclassification of Executive Officers' Salaries (Study by Department of Consumer Affairs) • Recognition of Board Staff who Developed Website
SEPTEMBER 20	**Committee Meeting** • Strategic Plan Finalization • Evaluation of Committee's Progress in Reaching Strategic Goals • Expand the Board's Space to Meet Operational Needs • Pursue BCPs for Identified Program Needs • Reorganize Board Management Structure to Oversee Programs and Staff • Pursue DCA's Regulatory Change regarding Declaratory Letters and Conflict of Interest for Inspectors • Personnel Update and Budget Report • Amendment to Policy and Procedure Manual for Board Members • Review of Agenda for October 2000 Board Meeting

2001	
JANUARY 4	**Committee Meeting** • Evaluation of Committee's Progress in Reaching Strategic Goals • Review of Agenda for January 2001 Board Meeting • California Bureau of State Audits Report of Consumer Protection Activities of the Department of Consumer Affairs • Personnel Update and Budget Report • Status of BCPs Submitted and AG Deficiency Augmentation Needed • Office Expansion Update
MARCH 15	**Committee Meeting** • Planning for Update of Board's Strategic Plan for 2001/02 • Evaluation of Committee's Progress in Reaching Strategic Goals • Draft Report by the California Bureau of State Audits on the Board of Pharmacy • Future Board Meeting Dates for 2002 • Personnel Update and Budget Report • AG Augmentation Request for 2000/01 Submitted • Process Delineation for Referring Matters to Board Policy Committees
APRIL 25 & 26	**Public Board Meeting** • Strategic Planning Update of Each Committees' Activities for 2001/02
JULY 3	**Committee Meeting** • Strategic Plan Revision and Adoption of 2001/02 Plan by Board • Strategic Plan Revision Plans for 2002/03; Add One Day to April 2002 Board Meeting • AG Augmentation Request for 2000/01 Approved at Deficient Level • Evaluation of Committee's Progress in Reaching Strategic Goals • Personnel Update and Budget Report • Committee Assignments of Board Members • Review of Agenda for July 2001 Board Meeting • Process Delineation for Referring Matters to Board Policy Committees – Reconsideration by Committee
SEPTEMBER 19	**Committee Meeting** • Evaluation of Committee's Progress in Reaching Strategic Goals • Personnel Update and Budget Report • Management Reorganization – Reclassification of One Staff Position to Manager Approved Substantially Reducing Span of Control
DECEMBER 3	**Committee Meeting** • Strategic Plan Update for 2002 – Consultant Needed • Evaluation of Committee's Progress in Reaching Strategic Goals • Personnel Update and Budget Report • Hiring Freeze Imposed, Board Impact and Strategies to Complete Work • All Inspector Positions Filled • Discussion of Department Overcharges for Division of Investigation Services

2002	
FEBRUARY 15	**Committee Meeting** • Preparation for Strategic Planning Session by Staff • Preparation for Strategic Planning Session by Board
MARCH 13	**Staff TCT Meeting and Input on Board Vision, Mission, Values and Environmental Scan** – Preparation for Strategic Planning Session by the Board
APRIL 8	**Committee Meeting** • Strategic Plan Revision for 2002/03 • Update of Committee's Strategic Goals • Personnel Update and Budget Report • Future Board Meeting Dates for 2003 • The Communications Team Report
APRIL 25 & 26	**Public Board Meeting** • Strategic Planning Session (Full Day) – Revision of Board Vision, Mission, Values, Environmental Scan and Restructuring of Board Plan • Identification of Strategic Goals for Each Board Committee

JULY 16	**Committee Meeting**
	• Strategic Plan Restructuring and update 2002/03
	• Update of Committee's Strategic Goals
	• Budget Issues for 2002/03
	  - Transfer of $6 million from the Board's Fund
	  - Elimination of Vacant Positions
	  - Hiring Freeze
	• Proposed Budget Change Proposals for 2002/03 and 2003/04
	• Sunset Report
	• Personnel Update and Budget Report

PART I

This section contains the board's responses to specific information requested by the Joint Legislative Sunset Review Committee as specified in Part I of their survey.

- Board History and Function
- Board Composition
- Board Committees and Their Functions
- License Types and Authority
- Major Studies Conducted by the Board
- Licensing Statistical Overview
- Public Disclosure of Licensee Information
- Budget and Staff
- Licensing Requirements
- Examination Information
- Application Processing Times
- Continuing Education/Competency Requirements
- Comity/Reciprocity with Other States
- Enforcement Program Overview
- Results of the Complainant Satisfaction Survey
- Enforcement Expenditures and Cost Recovery
- Restitution Provided to Consumers
- Complaint Disclosure Policy
- Consumer Outreach and Education, and Use of the Internet

Blank Intentionally

PART 1

Background Information and Overview of the Current Regulatory Program

This section contains the board's response to specific information requested by the Joint Legislative Sunset Review Committee's Sunset Review Survey – specifically Part I. For the committee's ease in reviewing this report, the information provided in this section follows the same order as requested in Part I of their survey.

BOARD HISTORY AND FUNCTION

The Board of Pharmacy was established in 1891 to protect the public by regulating those responsible for dispensing medications to the public. In the first six years, the board registered 1,063 pharmacists and 369 pharmacists' assistants. The board now also regulates those who wholesale prescription drugs or devices as well as entities that ship prescription drugs and devices to California patients or practitioners. The board has approximately 76,000 licensees in 12 license categories that include both personal and business licenses. However, the regulation of pharmacy through the licensure of pharmacists, pharmacies, and pharmacy technicians remains the primary focus of board activity, with consumer protection at the core of the board's operations.

The board is required by statute (Business and Professions Code 4011) to administer and enforce both the Pharmacy Law (Business and Professions Code 4000 et seq.) and the California Uniform Controlled Substances Act (Health and Safety Code 11000 et seq.). These statutes (and the associated regulations) generally address the acquisition, storage, distribution and dispensing of prescription drugs (including controlled substances) and devices. The interaction of these separate state and federal laws governing these same subjects (the Federal Food, Drug and Cosmetic Act [21USC301 et seq.] and the Controlled Substances Act [21USC801 et seq.] and their associated regulations and guidelines) result in considerable complexity to the board's regulatory mandate.

As a regulatory agency whose mandate is to protect the public, before issuing any license the board ensures that businesses are in compliance with specific rules and regulations, and that individuals satisfy the board's requirements for minimum competency as demonstrated through experience and/or achievement of a successful score on a licensure examination.

Since its creation, the scope of the board's authority has remained relatively constant, although the Legislature has expanded and contracted the board's regulatory obligations in response to trends in the healthcare marketplace. For example:

- Pharmacies that compound sterile injectable drug products will require a new license in 2003 pursuant to SB 293 (Torlakson and Figueroa, Chapter 827, Statutes of 2001).

- Medical device retailers were added in the late 1980s as a new licensing group to regulate non-pharmacies that furnish prescription devices (not drugs) and durable medical equipment (e.g., wheelchairs) prescribed to patients. This licensing program was shifted to the Department of Health Services in July 2001 by AB 1496 (Olberg, Chapter 837, Statutes of 2000).
- Veterinary food animal drug retailers were added in 1995 as a specialty class of drug wholesalers who distribute and label drugs prescribed by a veterinarian for use on food animals (AB 611, Chapter 350, Statutes of 1995).

The board also serves as a conduit for information to consumers and its licensees. It has taken several steps to fulfill its public education mandate. The board launched an award winning public education effort in 1997 that featured the placement of informative articles in local newspapers and participated in electronic media events relating to pharmacy. The board has also greatly expanded and improved its newsletter, *The Script,* and developed the *Health Notes* monograph series. Lastly, the board has a substantial Web site that contains a wide variety of information regarding board activities and offers electronic versions of board publications, applications, complaint forms, and license verification.

BOARD COMPOSITION

The board is comprised of 11 members: seven pharmacists and four public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. The nine other members (two public members and seven professional members) are appointed by the Governor.

The Business and Professions Code (section 4001) requires that at least five of the seven registered pharmacist appointees must be actively engaged in the practice of pharmacy and the board must include at least one practicing pharmacist from an acute care hospital, another from a community pharmacy, and one from a long-term care or skilled nursing facility. This balanced composition is important for the board to respond to the rapid evolution of health care in general, and managed care in particular, in seeking to reduce the costs of providing health care in all settings, including the costs of providing pharmaceutical care and products.

Table 1 – Board of Pharmacy Members

BOARD MEMBER	APPOINTED BY	TYPE	DATE APPOINTED	TERM	EXPIRES
Vacant	Governor	Public			June 2001
David Fong	Governor Davis	Pharmacist	January 16, 2002	1st	June 2005
Stanley Goldenberg	Governor Davis	Pharmacist	June 26, 2001	1st	June 2004
Don Gubbins	Governor Davis	Pharmacist	March 10, 2000	1st	June 2003
Clarence Hiura	Governor Davis	Pharmacist	June 8, 2001	1st	June 2004
John Jones	Governor Wilson Governor Davis	Pharmacist	June 3, 1998	2nd	June 2005
Steve Litsey	Governor Wilson	Pharmacist	May 28, 1998	1st	June 2002
William Powers	Senate Rules Committee	Public	June 1, 2000	1st	June 2004
John Tilley	Governor Davis	Pharmacist	June 8, 2001	1st	June 2004
Caleb Zia	Governor Wilson	Public	January 13, 1995	2nd	June 2002
Andrea Zinder	Assembly Speakers Villagarosa and Hertzberg	Public	May 14, 1999 completed term of another public member who resigned	1st	June2004

All board members actively participate in board activities, and the board has not experienced problems with establishing a quorum during a public board meeting. The board has been fortunate because its appointing authorities generally have promptly filled vacancies; Robert Elsner filled the one position on the board currently vacant until June 1, 2002, when Mr. Elsner's grace year expired.

The current size of the board promotes efficient decision making while permitting each member an opportunity to participate actively in board policy development during committee and board meetings. The balanced composition of the professional members of the board required by statutory law prevents over-representation from one practice setting, and public members are full participants in committee and board decision-making. The board believes that increasing the size of the board would not likely improve or speed the board's policy making processes, and instead could extend the period in which it takes to develop decisions and board policy since more members would wish provide comments. Decreasing the size of the board could result in an imbalance in composition and decision-making.

BOARD COMMITTEES AND THEIR FUNCTIONS

The board performs much of its work in committees; some committees are standing committees, others are task forces or ad hoc committees formed to examine a specific topic, then disbanded following completion of the task. The board also has two specialized standing committees — one with responsibility for the California pharmacist licensing examination (Competency Committee) and the other for issuing citations and fines for alleged violations of pharmacy laws (Citation and Fine Committee). Each of these committees is described on the following pages.

Policy Committees

The board's strategic plan establishes five standing committees through which the board establishes its goals and organizes its activities in pursuit of ensuring the public health, safety, and welfare, and to assure the provision of quality pharmacists' care.

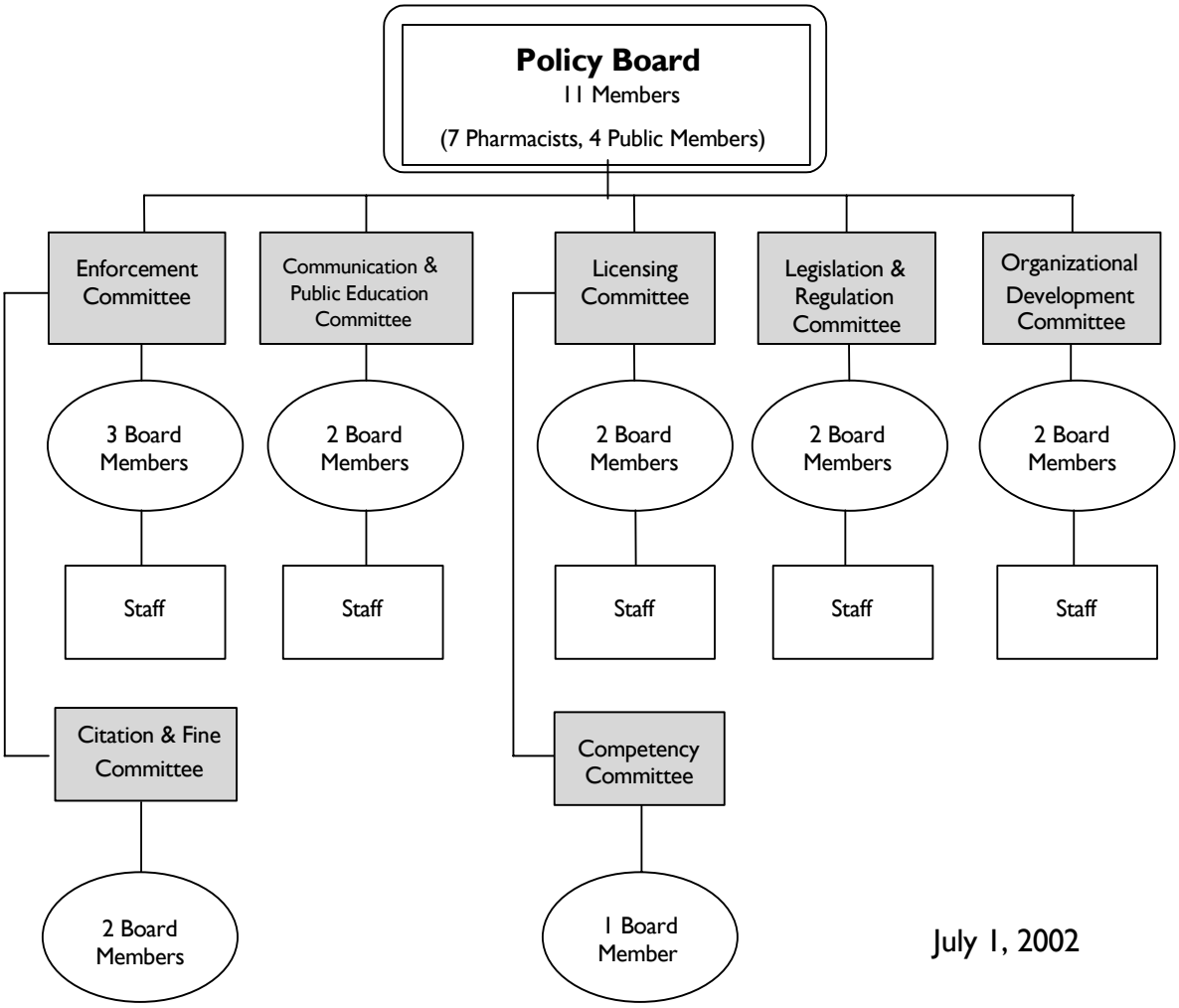


Figure B - Board Committees' Structure

BOARD COMMITTEES AND SUBCOMMITTEES

The board manages, plans, and tracks its operations through its strategic plan, which is annually updated and periodically reorganized (about every five years). The board's strategic plan establishes five standing committees through which the board articulates its goals and organizes its activities to ensure the public health, safety and welfare, and assure the provision of quality pharmacists' care. These five committees develop policy related to a board mission-related goal. *(The previous Board Committees section of this report describes the major activities of these five committees.)*

The committees and their goal areas are:

Licensing Committee

Goal: Ensure the professional qualifications of pharmacists and establish the minimum standards for board-licensed facilities. *Ensuring that the qualifications of those entering the practice of pharmacy, as well as those continuing to practice, meet minimum requirements for education, experience and knowledge; and ensuring that facilities licensed by the board meet minimum standards.*

Enforcement Committee

Goal: Exercise oversight on all pharmacy activities. *Protecting the public by preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.*

Communication and Public Education Committee

Goal: Proactively provide relevant information to consumers and pharmacists. *Encouraging the public to discuss their medications with their pharmacists; emphasizing the importance of patients complying with their prescription treatment regiments; and helping pharmacists to become better informed on subjects of importance to the public.*

Legislation and Regulation Committee

Goal: Advocate legislation and promulgate regulations that advance the board's vision and mission. *Pursuing legislation and regulations that ensure better patient care and providing effective regulation of the individuals and firms who handle, dispense furnish, ship and store prescription drugs and devices in California.*

Organizational Development Committee

Goal: Ensure the achievement of the board's mission and goals. *Conducting strategic planning, budget management, and staff development activities.*

Each of these committees is comprised of at least two board members (both public and professional members) and at least two staff members who provide technical and administrative input and support. The Enforcement Committee was expanded to three board members in July 2002. The committees are an important venue for ensuring that staff and board members share information and perspectives in crafting and implementing strategic objectives. Each committee meets quarterly prior to each board meeting and provides a report and minutes of the committee meeting during each board meeting. The Enforcement Committee is the only

committee that meets quarterly with the entire enforcement staff (in Enforcement Team meetings). When the Licensing Committee was expanded to three members for the first six months of 2002, all meetings of this committee became public, and were publicly noticed. Nevertheless, a committee report and minutes of the Licensing Committee meetings were still provided at board meetings. In July 2002, new committee assignments were made by the board president, who reduced the appointments to the Licensing Committee to two members and increased the appointments to the Enforcement Committee to three members. As such, all Enforcement Committee meetings will be public.

The board's committees allow board members and staff to discuss and conduct problem solving on issues related to the board's strategic goals and jurisdiction. They allow the board a deliberative process to consider options for implementing components for the strategic plan.

The committees are charged with coordinating board efforts to reach board goals and achieving positive results on performance measures.

The board president designates one of the board members assigned to a committee as the committee's chairperson. The chairperson coordinates the committee's work and ensures progress toward the board's priorities.

After detailed study of an issue during one or more committee meetings, the committees refer policy decisions to the full board for a formal decision and vote. During these discussions at board meetings, the public is encouraged to provide comments. Committee decisions do not become board policy until the topic is publicly noticed and discussed at a board meeting and voted upon by the full board.

At each board meeting, one of the board's committees holds a public meeting. Over the year, each committee has at least one such public committee meeting in conjunction with a board meeting. And over the last year, the board has begun to have more frequent public meetings of the Enforcement, Licensing, and Legislation and Regulation Committees. During the public committee meetings, comments from the public are strongly encouraged, and the meetings themselves are frequently public forums on specific issues before a committee.

A meeting summary is prepared following each committee meeting whether the meeting was a public meeting or not, and minutes are prepared. Because the committee process is an efficient means of doing business, the board was able to reduce the number of board meetings from five to four annually. It also became a resource issue; with the establishment of five policy committees that were meeting before each of the five annual board meetings, this added 20 new meetings that had to be staffed, scheduled, agendized, and recorded.

A calendar of the major activities of each of the board's strategic management committees is included in this section beginning on page 108. There is also a listing for each committee of every meeting and topics discussed in the *Board Committees* section of this report. Copies of the minutes and strategic activities of each committee are available from the board.

Competency Committee

The board's Competency Committee develops and grades the board's pharmacist licensure examination twice each year. The committee is comprised of representatives from a cross section of professional practice as well as representatives from each of California's schools of pharmacy. There are 18 members on this committee.

Membership on this committee is highly selective, professionally challenging, and time-consuming. The committee meets six times annually in two-day meetings. There is also a two-day annual goal setting session and item development tasks, and occasional subcommittee work. Membership is for a maximum of eight years, and appointment is by the board president based upon professional qualifications, recommendations, and pharmacy practice setting.

The Competency Committee is a stand-alone committee that is within the auspices of the board's Licensing Committee; one board member sits on this committee and provides updates on the status of the board's pharmacist examination during board meetings, including release of statistics describing the performance of candidates on the most recent exam. The board member is also the board's liaison to the committee.

Citation and Fine Committee

The Citation and Fine Committee functions as a subcommittee under the Enforcement Committee. The committee was established in April 2002 to issue citations and fines for any violation of pharmacy law. The Citation and Fine Committee replaced the board's long-standing Compliance Committees, and is comprised of two board members.

The Citation and Fine Committee reviews investigation reports prepared by board inspectors, and where warranted, issues citations and fines in accordance with California Code of Regulations section 1775. This regulation section became effective on July 22, 2001, and expands the types of violations subject to citation and fine by the board to any violation of pharmacy law. Previously, the board's regulations had authorized citation and fine authority only for failure to consult patients, unlicensed activity and for continuing education violations. The expanded authority to citation and fine is authorized to a committee of the board appointed by the board president. The authority to citation and fine for any violation of pharmacy law represents an aggressive consumer protection effort by the board to assure that less serious violations that do not warrant formal discipline through the Administrative Procedure Act are nevertheless handled in a serious manner by the board, and in a manner that results in licensees correcting the violations.

During promulgation of the regulation, the board had planned to implement the expanded citation and fine authority through the board's Compliance Committees. However, legal counsel advised the board that the Compliance Committee processes and procedures were not consistent with the provisions of section 1775, and might run afoul of the Government Code. A new process would be needed. Consequently, the board directed the formation of a new committee to investigate alleged violations and, if warranted, issue citations. This is an investigative, prosecutorial and/or advocacy function, performed in closed session by two board members. The committee's issuance of a citation is akin to the executive officer filing an accusation after reviewing an investigation.

The board simultaneously disbanded the Compliance Committees when it established the new Citation and Fine Committee to implement section 1775. As a new program, evaluation of the implementation of the regulation and the committee's actions will occur over the next year during discussions at board meetings.

The purpose of the Citation and Fine Committee is to determine whether a citation should be issued in particular cases. However, the committee does not determine the ultimate merits of an issued citation; such a determination occurs during the hearing process -- should a hearing be requested by a licensee to contest the issuance of the citation.

If a licensee requests a hearing to contest a citation or fine, the matter is moved forward in accordance with the hearing provisions of the Administrative Procedure Act. The Attorney General's Office represents the committee [as it does for the executive officer (who is the "complainant") for accusations] in the proceedings. The board members who participated as the Citation and Fine Committee must recuse themselves from all proceedings under appeal.

Prior to the implementation of the Citation and Fine Committee, the Compliance Committees, which were comprised of a Northern California Committee and a Southern California Committee, operated for more than 25 years as an alternative to the formal disciplinary process. Two to three board members convened these public meetings, which were held at least quarterly. Cases referred to the Compliance Committees were those where a licensee had violated pharmacy laws, but the violations were not serious enough to warrant a referral to the Attorney General's Office for formal discipline.

The intent of the committees was to obtain compliance and correction through a "peer review" process of board members. Each regional committee meeting was open to the public with a public agenda listing those who were scheduled to appear and minutes were prepared following the meeting. Since 1995, the Compliance Committees had issued citations and fines for violation of the patient consultation law.

SPECIAL SUBCOMMITTEES

The board's president may establish additional committees, whether standing or special, as he or she deems necessary. The composition of the committees and the appointment of the members are determined by the board president in consultation with the vice president, and the executive officer. Two special committees were formed since the board's last sunset review before the Legislature in 1996.

Medication Information Technology Subcommittee

Under the umbrella of the Communication and Public Education Committee, the board president appointed a special Medication Information Technology Subcommittee in 1999. The purpose of the committee was to collect information on new pharmacy compatible technological capabilities; identify privacy and confidentiality issues as they relate to technology and prescription medications; research and analyze California pharmacy law and regulations to determine what changes in laws and regulations are necessary to accommodate new technology

capabilities; identify the obstacles to patient-focused technology; and to make recommendations to the Board of Pharmacy in these areas.

Representatives from the profession and experts in the technology field participated in the four public subcommittee meetings. In April 2000, the subcommittee made three recommendations to the board; they were to amend pharmacy law to:

- authorize pharmacists to provide clinical advice or consultation from outside a pharmacy,
- include communication for clinical and consultative purposes as specific components in the pharmacist's scope of practice, and
- amend the board's regulation regarding the ability for a consumer to opt of having his or her prescription records in a common electronic file.

The board approved moving forward with all three recommendations. The first two recommendations required statutory changes, which the board sponsored in 2001 legislation and which became effective January 1, 2002; the third recommendation involves a regulation change which is awaiting action in a future rulemaking.

Pharmacy Manpower Task Force

To address the concerns of the board's stakeholders about a nationwide pharmacist shortage and the inability of many California pharmacy employers to hire pharmacists to adequately staff pharmacies in various parts of California, the board's president appointed a Pharmacy Manpower Task Force in December 2000. In forming the task force, the board acknowledged that a pharmacist shortage exists in California and stated concern on how the shortage impacts the availability and safe delivery of pharmacists' care to patients in the impacted areas now and in the future.

The Task Force functioned through the leadership of the Licensing Committee. The goal of the task force was to seek solutions to the pharmacist shortage and to coordinate the various efforts underway by other interested and affected parties. The board's purpose was to identify solutions that would ensure patients' futures access to pharmacists, pharmacists' care and prescription services.

A diverse group of individuals were appointed to this task force to obtain divergent opinions. In addition to the two board members from the board's Licensing Committee, the task force had four representatives from each of the schools of pharmacy and one representative from each of the following organizations: California Pharmacists Association, California Society of Health Systems Pharmacists, California Retailers Association, California Association of Health Plans, Pharmacists Planning Services Inc., the Guild for Professional Pharmacists, United Food and Commercial Workers, and the California Employee Pharmacists Association and a consumer representative. Additionally public input was solicited at every meeting.

The task force met publicly five times during 2001 at various locations throughout California, and issued its final report to the Board of Pharmacy in January 2002. The Task Force reviewed

27 proposed solutions. The Task Force agreed on 13 proposed solutions, they rejected three, and voted not to discuss 11.

The Licensing Committee reviewed all proposed solutions, and made recommendations to add 10 of the proposals to the board's strategic plan for 2002/03.

Calendar of Meetings Convened
1997 to Present

1997			
JAN	· Board Meeting · Pharmacist Licensure Examination · Consultation Day - Brown Bag Media Event	**JUL**	· Board Meeting · Pharmacist Licensure Examination (Grading)
FEB	· Roundtable Discussion on Prescribing Authority for Pharmacists · Pharmacist Licensure Examination (Grading)	**AUG**	· Inspector Workshop · Enforcement Committee Meeting · Licensing Committee Meeting · Competency Committee Annual Planning Meeting (Exam)
MAR	· Board Meeting · Competency Committee Meeting (Exam)	**SEP**	· Board Meeting · Northern Compliance Committee Meeting · Competency Committee Meeting (Exam) · Communication and Public Education Committee Meeting
APR	· Competency Committee Meeting (Exam)	**OCT**	· Competency Committee Meeting (Exam)
MAY	· Board Meeting · Organizational Development Committee Meeting - Strategic Planning	**NOV**	· Legislation and Regulation Committee Public Meeting · Southern Compliance Committee Meeting
JUN	· Pharmacist Licensure Examination · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting	**DEC**	· Competency Committee Meeting (Exam) · Licensing Committee Meeting · Northern Compliance Committee Meeting

1998			
JAN	· Board Meeting · Enforcement Team Meeting · Pharmacist Licensure Examination	**JUL**	· Board Meeting · Enforcement Committee Public Meeting · Pharmacist Licensure Examination (Grading) · Southern Compliance Committee Meeting
FEB	· Summit of Health Care Payers and Providers Workshop · Communication and Public Education Public Meeting · Licensing Committee Meeting · Pharmacist Licensure Examination (Grading)	**AUG**	· Competency Committee Annual Planning Meeting (Exam)
MAR	· Board Meeting · Board Strategic Planning · Legislation and Regulation Committee Meeting · Competency Committee Meeting (exam)	**SEP**	· Northern Compliance Committee Meeting · Competency Committee Meeting (Exam)
APR	· Organizational Workshop for Inspectors · Enforcement Committee Workshop · Licensing Committee Meeting · Summit on Health Care Payers and Providers · Southern Compliance Committee Meeting · Competency Committee Meeting (Exam)	**OCT**	· Board Meeting · Licensing Committee Meeting · Enforcement Team Meeting · Legislation and Regulation Committee Public Meeting · Competency Committee Meeting (Exam)
MAY	· Board Meeting · Licensing Committee Public Meeting · Competency Committee Meeting (Exam)	**NOV**	· Legislation and Regulation Committee Meeting
JUN	· Enforcement Team Meeting · Pharmacist Licensure Examination · Northern Compliance Committee Meeting	**DEC**	· Southern Compliance Committee Meeting

1999			
JAN	· Board Meeting · Enforcement Team Meeting · Licensing Committee Meeting · Communication and Public Education Committee Public Meeting · Legislation and Regulation Committee Meeting · Pharmacist Licensure Examination	**JUL**	· Board Meeting · Licensing Committee Public Meeting - Automation, Technology & Innovation · Licensing Committee Meeting · Communication and Public Education Committee - Medication Information Technology Task Force Meeting · Pharmacist Licensure Examination (Grading)
FEB	· Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Pharmacist Licensure Examination (Grading)	**AUG**	· Organizational Development Committee Meeting · Competency Committee Annual Planning Meeting
MAR	· Board Meeting · Organizational Development Committee Public Meeting - Strategic Planning · Enforcement Team Meeting · Licensing Committee Meeting · Competency Committee Meeting (Exam) · Legislation and Regulation Committee Meeting	**SEP**	· Licensing Committee Public Meeting · Pharmacy Manpower Forum · Enforcement Team Meeting · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Competency Subcommittee Meeting (Exam Regrades)
APR	· Communication and Public Education Committee Meeting · Licensing Committee Meeting · Northern Compliance Committee Meeting · Competency Committee Meeting (Exam)	**OCT**	· Board Meeting · Legislation and Regulation Committee Public Meeting · Communication and Public Education Committee Meeting · Organizational Development Committee Meeting · Competency Committee Meeting (Exam)
MAY	· Board Meeting · Enforcement Committee Public Meeting · Enforcement Team Meeting · Communication and Public Education Committee - Medication Information Technology Task Force Meeting	**NOV**	· CURES Workshop
JUN	· Pharmacist Licensure Examination · Enforcement Team Meeting · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting	**DEC**	· CURES Workshop · Enforcement Team Meeting · Legislation & Regulation Committee Meeting

2000			
JAN	· Board Meeting · Licensing Committee Public Meeting - Pharmacy Manpower Forum · Communication and Public Education Committee Public Meeting · Licensing Committee Meeting · Organizational Development Committee Meeting · Pharmacist Licensure Examination · Legislation and Regulation Committee Meeting	**JUL**	· Board Meeting · Competency Subcommittee Meeting (Preliminary Item Analysis) · Enforcement Committee Public Meeting · Pharmacist Licensure Examination (Grading)
FEB	· CURES Conference · CURES Workshop · Communication and Public Education Committee - Medication Information Technology Task Force Public Meeting · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Pharmacist Licensure Examination (Grading) · Competency Subcommittee Meeting (Preliminary Item Analysis)	**AUG**	· Competency Committee Annual Planning Meeting
MAR	· Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Exam Regrades) · CURES Workshop · Enforcement Team Meeting · Licensing Committee Meeting · Organizational Development Committee Meeting · Legislation and Regulation Committee Meeting	**SEP**	· Organizational Development Committee Meeting · Enforcement Team Meeting · Communication and Public Education Committee Meeting · Legislation and Regulation Committee Meeting · Southern Compliance Committee Meetings (2) · Northern Compliance Committee Meeting · Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Exam Regrades)
*	*April, May and June 2000 continue on the next page.*	*	*October, November and December 2000 continue on the next page.*

2000 (CONTINUED)			
APR	· Board Meeting · Organizational Development Committee Public Meeting - Strategic Planning	**OCT**	· Board Meeting · Legislation and Regulation Public Committee Meeting · Licensing Committee Meeting · Southern Compliance Committee Meeting · Competency Committee Meeting (Exam)
MAY	· Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Competency Committee Meeting (Exam)	**NOV**	· Northern Compliance Committee Meeting
JUN	· Enforcement Team Meeting · Licensing Committee Meeting · Pharmacist Licensure Examination · Legislation and Regulation Committee Meeting · Organizational Development Committee Meeting	**DEC**	· Enforcement Team Meeting
*	*July, August and September 2000 continue on the previous page, second column.*		

2001			
JAN	· Board Meeting · Pharmacy Manpower Task Force Public Meeting · Licensing Committee Meeting · Communication and Public Education Committee Meeting · Communication and Public Education Committee Public Meeting · Pharmacist Licensure Examination · Organizational Development Committee Meeting · Northern Compliance Committee Meeting · Legislation and Regulation Committee Meeting	**JUL**	· Board Meeting · Legislation and Regulation Committee Meeting · Pharmacy Manpower Task Force Public Meeting · Organizational Development Committee Meeting · Pharmacist Licensure Examination (Grading) · Competency Subcommittee Meeting (Preliminary Item Analysis) · Southern Compliance Committee Meeting · Northern Compliance Committee Meeting
FEB	· Pharmacist Licensure Examination (Grading) · Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Preliminary Item Analysis)	**AUG**	· Southern Compliance Committee Meeting · Northern Compliance Committee Meeting · Competency Committee Annual Planning Meeting
MAR	· Enforcement Committee Public Meeting · Enforcement Team Meeting · Organizational Development Committee Meeting	**SEP**	· Enforcement Committee Public Meeting · Enforcement Team Meeting · Legislation and Regulation Committee Meeting · Organizational Development Committee Meeting · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Exam Regrades)
*	*April, May and June 2001 continue on the next page.*	*	*October, November and December 2001 continue on the next page.*

2001 (continued)

APR	· Board Meeting · Organizational Development Committee Public Meeting – Strategic Planning · Licensing Committee Meeting · Pharmacy Manpower Task Force Meeting · Communication and Public Education Committee Meeting · Legislation and Regulation Committee Meeting · Northern Compliance Committee Meeting Southern Compliance Committee Meeting · Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Exam Regrades)	**OCT**	· Board Meeting · Legislation and Regulation Committee Public Meeting · Licensing Committee Meeting · Pharmacy Manpower Task Force Public Meeting · Communication and Public Education Committee Meeting · Southern Compliance Committee Meetings (2) · Competency Committee Meeting (Exam)
MAY	· Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Competency Committee Meeting (Exam)	**NOV**	· Northern Compliance Committee Meeting · Southern Compliance Committee Meetings (2)
JUN	· Pharmacy Manpower Task Force Public Meeting · Enforcement Team Meeting · Licensing Committee Meeting · Pharmacist Licensure Examination	**DEC**	· Enforcement Team Meeting · Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Licensing Committee Meeting · Communication and Public Education Committee Meeting · Organizational Development Committee Meeting
*	*July, August and September 2001 continue on the previous page, second column.*		

2002

JAN	· Board Meeting · Communication and Public Education Committee Meeting · Legislation and Regulation Committee Public Meeting · Pharmacist Licensure Examination · Southern Compliance Committee Meeting	**JUL**	· Board Meeting · Citation and Fine Committee Meetings (2) · Enforcement Committee Public Meeting · Enforcement Team Meeting · Pharmacist Licensure Examination (Grading) · Competency Subcommittee Meeting (Preliminary Item Analysis) · Organizational Development Committee Meeting
FEB	· Northern Compliance Committee Meeting · Southern Compliance Committee Meeting · Competency Subcommittee Meeting (Preliminary Item Analysis) · Pharmacist Licensure Examination (Grading) · Competency Committee Meeting (Exam) · Organizational Development Committee Meeting	**AUG**	· Competency Committee Annual Planning Meeting
MAR	· Licensing Committee Public Meeting · Enforcement Committee Public Meeting · Enforcement Team Meeting · Communication and Education Committee Public Meeting · Southern Compliance Committee Meetings (2) · Northern Compliance Committee Meeting · Competency Subcommittee Meeting (Exam Regrades)	**SEP**	· Enforcement Committee Public Meeting · Enforcement Team Meeting · Competency Committee Meeting (Exam) · Competency Subcommittee Meeting (Exam Regrades) · Licensing Committee Public Meeting · Organizational Development Committee Meeting · Communication and Public Education Committee Meeting
APR	· Board Meeting · Organizational Development Committee Public Meeting – Strategic Planning · Organizational Development Committee Meeting · Legislation and Regulation Committee Meeting · Southern Compliance Committee Meetings (2) · Northern Compliance Committee Meeting · Competency Committee Meeting (Exam)	**OCT**	· Board Meeting · Legislation and Regulation Committee Public Meeting · Competency Committee Meeting (Exam)
MAY	· Competency Committee Meeting (Exam) · Citation and Fine Committee Meetings (2)	**NOV**	
JUN	· Citation and Fine Committee Meeting · Licensing Committee Public Meeting · Legislation and Regulation Committee Meeting · Pharmacist Licensure Examination	**DEC**	· Enforcement Committee Public Meeting · Enforcement Team Meeting

LICENSE TYPES AND AUTHORITY

Prescription drugs that save lives alleviate pain, and cure illnesses may also kill or produce harmful effects if the drugs are not dispensed and used properly. The board regulates the individuals dispensing prescription drugs and devices, and the facilities dispensing, selling, and storing of drugs to provide public safety and confidence in the prescription drug products, the care patients receive, and to prevent diversion of drugs to illicit markets.

The practice of pharmacy is a complex and highly regulated profession. The board regulates the practitioner (the pharmacist), the practice site (the pharmacy), and the product (the prescription drugs and devices that are dispensed), including the drug manufacturer and wholesaler.

As part of the application process for site licenses, the board confirms ownership information to assure the true beneficial ownership of every location. The top five owners, officers, and managers of these facilities require federal and state fingerprint clearances.

Table 2 - License Types and Authority

LICENSE TYPES AND AUTHORITY		
Title	Authority	Definition
Pharmacist	B & P 4051	An individual licensed by the board who has qualified to practice pharmacy on the basis of education, training and demonstrating minimum competency via passage of an examination.
Intern Pharmacist	B & P 4005 (a) CCR 1727	An individual registered with the board who is gaining the supervised practice experience necessary for licensure as a pharmacist.
Pharmacy Technician	B & P 4115 (e)(1)	An individual who assists a registered pharmacist in a pharmacy by performing non-judgmental functions under the direct supervision of a pharmacist.
Exemptee · Drug Wholesaler · Veterinary Food Animal Drug · Medical Device Retailer (until 7/1/01)	B & P 4053	A non-pharmacist who is responsible for the furnishing functions and operations performed by medical device retailers, drug wholesalers, manufacturers, hem dialysis and veterinary food animal drug retailers. Effective July 1, 2001, the regulatory authority over medical device retailer exemptees and medical device retailer premises was transferred to the Department of Health Services.

Table 2 - License Types and Authority (continued)

LICENSE TYPES AND AUTHORITY (CONTINUED)		
Title	Authority	Definition
Pharmacy · Community · Licensed Correctional Facility · Hospital · Exempt Hospital (smaller hospitals where a pharmacist is not required to be present) · Government Owned	B & P 4110 B & P 4056	The premises where controlled substances and prescription drugs or devices are stored, possessed, prepared, manufactured, derived, repackaged, furnished, sold or dispensed at retail to patients.
Sterile Compounding Pharmacy	B & P 4127.1 B & P 4127.2	A pharmacy compounding injectable sterile drug products in this state or a non-resident pharmacy compounding injectable sterile drug products for shipment into California.
Non-Resident Pharmacy	B & P 4120	Any U.S. pharmacy located outside of California that ships, mails or delivers, in any manner, controlled substances or prescription drugs into California to patients.
Clinic · Surgical Clinic · Non-Profit Clinic · Tribal Clinic · Student Health Center	B & P 4190 B & P 4180	A clinic that purchases drugs at wholesale prices for administration or dispensing to patients registered for care at the clinic.
Out of State Distributor	B & P 4161 B & P 4162	Premises located outside California that distribute prescription drugs or devices into California to wholesalers or licensed practitioners through any person or business other than a California-licensed wholesaler.
Hypodermic Needle and Syringe · Mercury Thermometer	B & P 4140	Any firm that sells hypodermic needles and syringes for use for animals and poultry if the firm is not otherwise licensed by the board as a pharmacy. Since July 1, 2002, any retailer, including pharmacies, distributing mercury thermometers must also obtain this license.
Drug Wholesaler · Premises · Custom Brokers · Reverse Distributors · Dialysis	B & P 4160 B & P 4054	A firm or individual that sells or distributes prescription drugs and devices that has been manufactured by another firm and will be provided to patients through pharmacies, medical device retailers or prescribers. Drug wholesalers do not sell drugs directly to patients. A reverse distributor is any person who acts as a agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Dialysis patients may receive dialysis prescription drugs and dialysis medical devices directly from a wholesaler or manufacturer.

Table 2 - License Types and Authority (continued)

LICENSE TYPES AND AUTHORITY (CONTINUED)		
Title	**Authority**	**Definition**
Veterinary Food Animal Drug Retailer	B & P 4196	Specialized licensed drug wholesalers who may label drugs prescribed by veterinarians for use on animals that are raised as food or to produce food.

Table 3 - Transferred License Authority

TRANSFERRED LICENSE AUTHORITY		
Title	**Authority**	**Definition**
Medical Device Retailer • Premises • Medical Device Warehouse	B & P 4130	Any premises, approved by the board where prescription devices are stored, possessed, prepared, manufactured, or repackaged and from which the prescription devices are furnished, sold or dispensed at retail. ***Effective July 1, 2001, this regulatory authority and program were transferred to the Department of Health Services.***

MAJOR STUDIES CONDUCTED BY THE BOARD

Over the last six years, the board has prepared a number of special reports. Additionally, several reports about the board have been prepared by other agencies. These reports and studies are listed below in an annotated format. Copies of the reports will be provided to the Joint Sunset Review Committee along with this report. Copies of these documents also can be obtained from the board.

List of Reports

➢ **Prepared By The Board:**

- *A Job Analysis Study of the California Pharmacist, April 2000* (Job Analysis for the California Pharmacist Examination) – Conducted in late 1999 via written surveys of approximately 900 pharmacists in California, this job analysis has been used to construct pharmacist licensure exams beginning with the June 2001 exam.
- *Audit of the North American Pharmacist Licensure Examination (NAPLEX), June 7, 2001;* this study was contracted by the board using four nationally known psychometric experts in occupational licensing from throughout the United States, this group evaluated the national pharmacist exam used by the 49 other states to determine if the exam met California's requirements for high stakes occupational licensing. The conclusion of the group is that the NAPLEX is a valid assessment of pharmacists' knowledge.
- *Board of Pharmacy, Board Member Procedure Manual, 1998.* This handbook for Board of Pharmacy members describes a diversity of board procedures and policies to aid board members in performing their duties.

- *Business Continuity Plan of the California State Board of Pharmacy, 1999 and revised 2002.* This volume contains the plan to restore and resume business functions after a "disaster" that disrupts the board's operations.
- *Consumer Awareness and Opinion Survey for the California State Board of Pharmacy, March 2000*, Performed by META. This contracted study involved telephone interviews of 750 individuals to learn how much they know about the Board of Pharmacy and its role in consumer protection, the role of pharmacists, and the importance of following drug treatment regimens. This survey formed a basis upon which the board will develop future consumer outreach programs.
- *Fee Structure Analysis and Recommendations, December 1998*, Market Value Planners. This fee audit of all board fees indicates that generally board fees are close to the board's costs of providing the services, the exceptions are that technician, intern and regrade fees are substantially too low for their costs, and the license fees from facilities generally subsidize a portion of the licensure fees of individuals (pharmacists, technicians, interns).
- *Operational Recovery Plan, Board of Pharmacy, 2001.* This volume details the board's plans to restore its computers and restore operations in the event of a disaster that prevents normal ongoing business functions.
- *Pharmacy Manpower Task Force, November 12, 2001.* This report provides the final recommendations as well as minutes from the six meetings of the task force throughout 2001, as the diverse group of task force members develop solutions to assure patients will continue to have access to pharmacists given a growing manpower shortage and projections for huge increases in the number of prescriptions that will need to be filled in the next few years.
- *Report of the Conference on Monitoring and Regulating Schedule II Controlled Substances, February 4, 2000.* This report summarizes the testimony of participants at this board-sponsored conference of federal and state regulators, law enforcement agencies, pain treatment advocates and health care providers and legislators to discuss possible options for providing increased pain relief to patients while preventing diversion of Schedule II controlled drugs.
- *The Board of Pharmacy Business Process Documentation,* 1997. Documents the business processes of the board to assist in identifying requirements for a proposed new automation system for the DCA.

➢ **Prepared About the Board:**

- *California Bureau of State Audits: State of California: Internal Control and State and Federal Compliance Audit Report for the Year Ended June 30, 1999.* The board was one of multiple agencies audited for internal controls. The board's procedures for cashiering fees, hiring proctors and purchasing postage for newsletter mailings were examined: most of the recommendations about the board involved services provided by the Department of Consumer Affairs, which took action on the auditor's recommendations.
- *California Bureau of State Audits: Investigations of Improper Activities by State Employees July 2000 Through January 2001 – Chapter 4.* This report of "whistleblower" complaints to

the Bureau of State Audits focused principally on the board's backlog of complaints in January 2000, when 1,500 complaints were pending. The report sharply criticizes the board for the backlog, but notes that had investigator positions been filled, there would have been no backlog. By the time the bureau's report was released in mid-2001, the number of pending complaints had been substantially reduced and most of the oldest complaints resolved.

- *Department of Consumer Affairs, Division of Investigation, Report on Investigation and Findings of the Board of Pharmacy, February 8, 1998.* This report summarizes the department's Internal Affairs investigation into anonymous complaints of board mismanagement during 1997. No criminal or major findings of mismanagement were identified.

➢ **Major Publications Produced:**

- *Disciplinary Guidelines*, as required by the Administrative Procedure Act, the board revised its *Disciplinary Guidelines* in 2001 via a rulemaking proceeding, and then published this updated volume of the guidelines that are used by the Attorney General's Office, Office of Administrative Law, board staff, board members and respondents' counsel in formulating disciplinary settlements.
- *Making the Case, 1998*, details how to establish and host a summit to educate third party payers on the cost/benefits of paying pharmacists for cognitive services such as drug management for anticoagulation therapy, hypertension, or diabetes as offsetting (and reducing) treatment costs overall. This volume was produced following the board's sponsorship of a summit on this subject in 1998.
- *Pharmacy Lawbooks*, two separate volumes (also available in a CD-format), published in 1998 and late 2000.
- *Strategic Plans for the California Board of Pharmacy, 1997/98, 1998/99, 1999/00, 2000/01 and 2001/02* (five volumes, only the 2001/02 is provided).
- *Health Notes* – Five new issues have been published since 1997 – Anticoagulation Therapy, Women's Health, Care of Developmentally Disabled Adults and Children, Alternative Medicines, and Quality Assurance Programs, which joins the 1996 publication of Pain Management. A seventh issue should be released by January 2003 on Geriatrics. These monographs provide board policy and updated information in drug therapies in these areas, and pharmacists can earn continuing education credit for leaning this information by submitting an examination.
- *The Script* – Eighteen issues have been published and distributed since January 1997. These newsletters are important methods for the board to communicate with licensees, and among the articles are updates on pharmacy law and regulation changes, answers to questions asked frequently of the board, and formal disciplinary actions taken by the board.
- *Prescription Drug Discount Program for Medicare Patients* – a brochure developed for patients who may be able to save money on prescription medication if they are Medicare patients who must pay for their own prescription medication. The board's brochure was the primary source of information used by seniors' groups and others to get the word out about this legislatively established program.

LICENSING STATISTICAL OVERVIEW

The number of applications received each year has generally increased since 1998/99, despite the board losing the medical device retailer (MDR) and MDR exemptee program after 2000/01.

Since 1998/99, the board has received increasing numbers of applications from:

- pharmacy technicians (up 156 percent),
- pharmacies (up 146 percent),
- pharmacy interns (up 142 percent),
- foreign graduates (up 123 percent), and
- pharmacists (up 108 percent).

Table 4 - Applications Received

APPLICATIONS RECEIVED	FISCAL YEAR			
	98/99	99/00	00/01	01/02
Change of Permit	353	320	994	580
Clinic	191	83	123	117
Exempt Hospital Pharmacy	n/a	1	3	5
Exemptee	1,029	925	1,230	400
Foreign Grad Evaluation	118	151	152	145
Hospital	91	45	36	60
Hypodermic Needle	18	20	38	14
Intern	1,083	1,267	1,449	1,535
Licensed Correctional Facility	0	0	2	2
Medical Device Retailer	152	163	191	0
Non Resident Pharmacy	24	40	45	47
Out of State Distributor	65	57	68	61
Pharmacist	1,700	1,585	1,756	1,844
Pharmacy	328	565	564	479
Pharmacy Technician	3,354	3,798	4,023	5,217
Vet Retailer	0	14	2	0
Wholesaler	88	130	89	86
TOTAL	8,594	9,164	10,765	10,592

n/a not applicable

The board denies licensure to a few applicants each year; since 1998/99, nearly 55 percent of the applications denied by the board were from pharmacy technician applicants. However, in 2001/02, 60 percent of the applicants denied were from pharmacy applicants.

Table 5 – Applications Denied

APPLICATIONS DENIED	FISCAL YEAR			
	98/99	99/00	00/01	01/02
Change of Permit	0	0	0	0
Clinic	0	0	0	0
Exempt Hospital Pharmacy	0	0	0	0
Exemptee	4	0	2	1
Hospital	0	1	0	0
Hypodermic Needle	0	0	0	0
Intern	1	0	0	1
Licensed Correctional Facility	0	0	0	0
Medical Device Retailer	1	1	0	0
Non Resident Pharmacy	0	0	0	0
Out of State Distributor	0	1	0	0
Pharmacist	6	0	4	1
Pharmacy	4	5	0	21
Pharmacy Technician	23	29	13	9
Vet Retailer	0	0	0	0
Wholesaler	2	0	0	1
TOTAL	41	37	19	34

The board has more pharmacy technician licensees than any other group. The board's licensee population has increased steadily over the last few years and is up 113 percent of 1998/99's licensees.

Table 6 –Total Licensees

TOTAL LICENSES	FISCAL YEAR			
	98/99	99/00	00/01	01/02
Clinic	502	578	624	710
Exempt Hospital Pharmacy	44	49	49	53
Exemptee	2,270	2,456	2,621	1,499
Hospital	552	550	527	519
Hypodermic Needle	361	365	308	305
Intern	2,884	3,290	3,481	3,674
Licensed Correctional Facility	41	41	42	43
Medical Device Retailer	526	596	662	n/a
Non Resident Pharmacy	153	168	166	187
Out of State Distributor	290	324	319	332
Pharmacist	29,342	29,650	30,110	30,962
Pharmacy	5,400	5,416	5,410	5,509
Pharmacy Technician	24,134	26,759	28,592	31,235
Vet Retailer	11	13	15	17
Wholesaler	475	515	504	507
TOTAL	66,985	70,770	73,430	75,552

As with all other licensing statistics presented in this section, the number of licenses renewed each year continues to climb (the pharmacy technicians and pharmacist licenses renew biennially so there is a two-year period to use to track the increase in these renewals).

Table 7- Renewed Licenses

RENEWED LICENSES	FISCAL YEAR			
	98/99	99/00	00/01	01/02
Clinic	396	443	528	547
Exempt Hospital Pharmacy	39	38	41	45
Exemptee	1,471	1,629	1,595	1,139
Hospital	552	521	500	485
Hypodermic Needle	296	256	238	224
Intern*	0	0	0	0
Licensed Correctional Facility	39	40	42	41
Medical Device Retailer **	365	399	404	3
Non Resident Pharmacy	93	101	115	120
Out of State Distributor	210	216	242	225
Pharmacist	12,573	13,027	12,635	13,534
Pharmacy	5,059	5,002	5,103	5,166
Pharmacy Technician	11,092	9,279	12,752	11,793
Vet Retailer	0	9	13	13
Wholesaler	377	363	369	386
TOTAL	32,562	31,323	34,577	33,721

* Non renewal permit
** Transferred to Department of Health Services July 1, 2001.

The number of licenses issued each year also has increased over four years and is up 110 percent from 1998/99. Over the four years the number of California licensed pharmacists has increased by 1,620 (from 29,342 to 30,962) although the board issued 3,407 new pharmacist licenses during the same period.

Table 8 - Licenses Issued

LICENSES ISSUED	FISCAL YEAR			
	98/99	99/00	00/01	01/02
Clinic	111	103	92	118
Exempt Hospital Pharmacy	5	7	3	7
Exemptee	626	646	584	409
Hospital	31	52	30	43
Hypodermic Needle	13	22	4	14
Intern	1,327	1492	1,439	1,650
Licensed Correctional Facility	2	0	2	1
Medical Device Retailer	145	139	147	37
Non Resident Pharmacy	35	37	47	44
Out of State Distributor	54	55	44	55
Pharmacist	743	779	899	986
Pharmacy	487	565	454	521
Pharmacy Technician	3,649	3,905	3,773	4,239
Vet Retailer	7	7	1	0
Wholesaler	63	96	58	92
TOTAL	7,298	7,905	7,577	8,216

PUBLIC DISCLOSURE OF LICENSEE INFORMATION

The board's public disclosure policy requires that the board release the name, license number and type of license, and the address of record of a licensee, pursuant to a written request. The board does not release other personal information about licensees, including the degree and date conferred. No information is disclosed about an applicant, including even if an application has been submitted.

License verification is a daily activity and can take place orally, via written request or via the board's Web site. The board will verify licensure of an individual or firm over the telephone by the name or license number of a licensee. This is especially important in the health care field since none of the board's licensees can practice or operate without active licenses. This is reinforced by accreditation standards of health facilities by the Joint Commission on Accreditation of Healthcare Organizations that require all staff to hold active licenses. Additionally drug wholesalers will not ship prescription drugs to pharmacies unless the pharmacy has a current, active license. The board's Web site demonstrates the importance of license verification -- the board's license verification feature on its Web site had more than 270,000 hits during 2001/02, which is high given that the board has only 76,000 licensees.

Requests for prior disciplinary information on licensees must be requested in writing. The board will release public documents regarding formal discipline (stipulations, decisions, accusations, interim suspension orders), copies of minutes from Compliance Committees involving a licensee, and a summary of substantiated violations where a board investigation or mediation was completed in the last five years. The board also releases citations and fines that it has issued. The board does not release information about unsubstantiated or non-jurisdictional complaints. The board's complaint disclosure policy also requires disclosure of corrections ordered during inspections by board staff.

Individuals seeking a list of licensees, or a list of licensees in a particular area, can obtain mailing lists for a fee by contacting the department's Public Sales Unit in the Information Services Division.

BUDGET AND STAFF

Primary Revenue Sources and Fee Setting

The board is wholly funded from the revenue it collects. The origin of the board's revenue of $5.8 million for 2001/02 is displayed graphically in Figure C below.

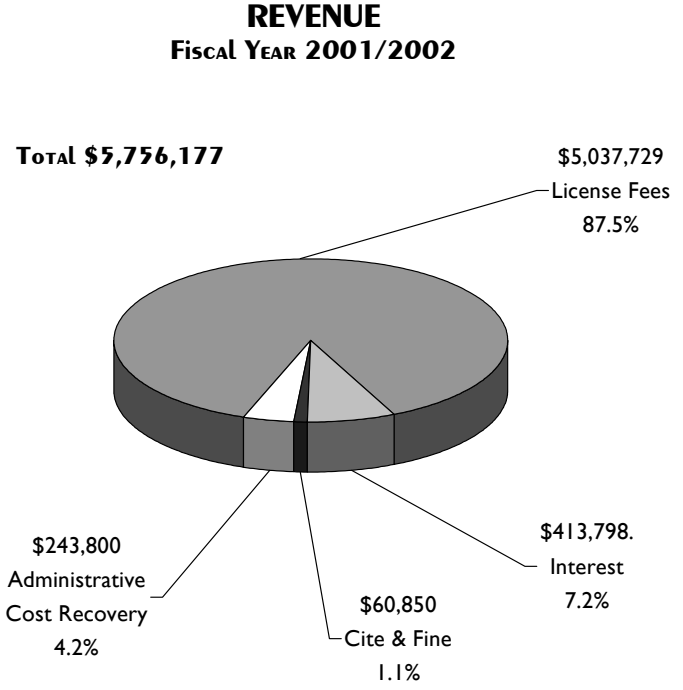


Figure C –Revenue Fiscal Year 2001/02

Licensure fees provide the greatest amount of funding; 26 percent ($1,294,140) of these fees are from application fees, the other 74 percent ($3,743,589) are from renewal fees.

By licensure program, fees are obtained principally from:

- Pharmacists 39.6 percent
- Pharmacies 25.0 percent
- Pharmacy Technicians 16.9 percent
- Wholesalers/Out Of State Distributors 8.5 percent
- All Remaining Programs 10.0 percent

Board fees collected by license type for 2001/02 are graphically displayed in Figure D below.

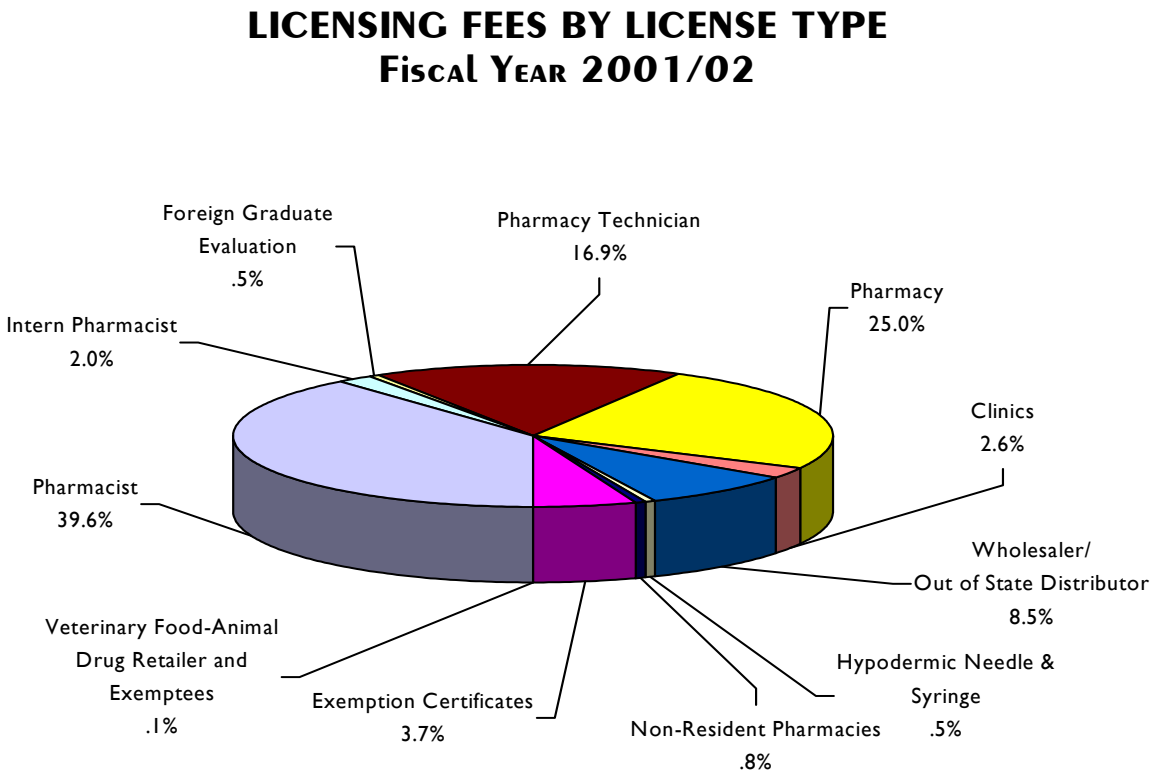


Figure D – Licensing Fees By License Type, Fiscal Year 2001/02

Fees by License Type

The board's fees are generally low, and currently fees are at the statutory minimum for most of the board's licensure categories. For example, pharmacists pay $110 for a two-year renewal of their pharmacist license. The board's last fee change was effective July 1, 1999, when the board reduced fees to their current levels. The board reduced fees because there was a growing reserve in the board's Contingency Fund, which was augmented via repayment of the 1991/92 General Fund transfer in several installments since 1995.

All board licenses expire on a continuous basis, so workload and revenue flow associated with processing renewal licenses is spread out over the year. Pharmacists and pharmacy technicians renew their licenses every two years in their birth month. All other permits issued by the board must be renewed annually.

During the 2002/03 budget deliberations, the Legislature's Conference Committee transferred $6 million from the board's Contingency Fund. The transfer of this money, unless repaid early in the 2003/04 fiscal year, will require the board to reduce expenditures substantially or to increase fees to their statutory maximum early in 2003/04.

Annual revenue since 1999/00 (when the fee reduction took effect) has been at least $1.3 million less than annual expenditures -- this

Table 9 –License Fees, Fiscal Year 2002/03

License Type	Current Fee	Statutory Limit
Pharmacist		
◆ Examination fee	$155.00	$185.00
◆ Regrading fee	75.00	85.00
◆ Issuance fee	115.00	150.00
◆ Biennial renewal fee	115.00	150.00
◆ Delinquency fee*	57.50	75.00
Intern Pharmacist		
◆ Issuance and extension fee	65.00	75.00
Foreign Education Pharmacist		
◆ Evaluation fee	165.00	175.00
Pharmacy Technician		
◆ Processing and issuance fee	50.00	50.00
◆ Biennial renewal fee	50.00	50.00
◆ Delinquency fee *	25.00	25.00
Exemption Certificate – Wholesaler		
◆ Application and investigation fee	75.00	100.00
◆ Issuance fee	110.00	150.00
◆ Annual renewal fee	110.00	150.00
◆ Delinquency fee *	55.00	55.00
Exemption Certificate – Vet Retailer		
◆ Application and investigation fee	100.00	100.00
◆ Issuance fee	150.00	150.00
◆ Annual renewal fee	110.00	150.00
◆ Delinquency fee *	55.00	55.00
Pharmacies – In and Out-of-State		
◆ Application fee	340.00	400.00
◆ Annual renewal fee	175.00	250.00
◆ Delinquency fee*	87.50	125.00
◆ Temporary permit	175.00	175.00
Clinics		
◆ Application fee	340.00	400.00
◆ Annual renewal fee	175.00	250.00
◆ Delinquency fee*	87.50	125.00
Hypodermic Needle & Syringe		
◆ Application fee	90.00	125.00
◆ Annual renewal fee	90.00	125.00
◆ Delinquency fee*	45.00	62.50
Wholesalers – In and Out-of-State		
◆ Application fee	550.00	600.00
◆ Annual renewal fee	550.00	600.00
◆ Delinquency fee*	150.00	150.00
Veterinary Food-Animal Drug Retailer		
◆ Application fee	400.00	400.00
◆ Annual renewal fee	250.00	250.00
◆ Delinquency fee*	125.00	125.00

imbalance was planned as a means to reduce the reserve in the board's fund. If the board waits until late 2003/04 to increase fees or if the Legislature waits that long to repay the loan, the board will be in a deficit situation. Consequently, the board has two options if the loaned money is not repaid before early 2003/04 – increase fees or reduce expenditures. The board will need to reduce annual expenditures by $2.3 million in 2002/03 and ongoing years to have revenue equal expenditures.

Table 9 –License Fees, Fiscal Year 2002/03 (continued)

License Type (continued)	Current Fee	Statutory Limit
Retired Pharmacist License	$30.00	$30.00
Continuing Education Provider		
◆ Registration fee	100.00	130.00
◆ Annual renewal fee	100.00	130.00
◆ Delinquency fee *	50.00	65.00
Continuing Education Course Approval		
◆ Evaluation of coursework	40.00	40.00
Reissue of Certificate (change of permit)		
◆ Name change, lost, stolen, destroyed	30.00	30.00
◆ Change of information	60.00	100.00
Transfer or License Certification		
◆ Intern hours	10.00	20.00
◆ License verification	10.00	20.00

*Section 163.5 of the Business and Professions Code provides that generally, the delinquency, penalty, or late fee for any licensee is 50 percent of the renewal fee but not less than $25 nor more than $150.

The board will ultimately need to seek a statutory increase to correct this imbalance since the board's fees, even at their maximum, are low. For example, the board charged $175 to renew a medical device retailer license (the medical device retailer program transferred to the Department of Health Services on July 1, 2002), while the Department of Health Services currently charges $850 to renew the same permit.

Revenue and Expenditure History

The board's revenue and expenditures are displayed below. Revenue exceeded expenditures in years where the fees were at higher levels (before July 1, 1999) or during those years that the board received a repayment of the 1991/92 borrowed money.

In 1999/00, 2001/02 and as projected in future years, expenditures <u>substantially</u> exceed revenue at current fee levels.

Table 10 - Actual and Projected Revenues

Revenues	Actual				Projected	
	FY 98/99	FY 99/00	FY 00/01	FY 01/02	FY 02/03	FY 03/04
Licensing Fees	$5,757,185	$5,122,003	$5,294,189	$5,037,729	$4,575,125	$4,668,965
Fines & Penalties	$90,320	$68,716	$85,643	$60,850	$54,765	$61,060
Other	$3,814,567*	$34,977	$1,235,169**	$243,800	--	--
Interest	$546,106	$627,840	$772,676	$413,798	$540,548	$301,241
TOTALS	**$10,208,178**	**$5,853,536**	**$7,387,677**	**$5,756,177**	**$5,170,438**	**$5,031,266**

* Includes $3,798,197 repaid from FY 1991/92 General Fund transfer.
** Includes $1,213,501 repaid from FY 1991/92 General Fund transfer.

Table 11 - Actual and Projected Expenditures

EXPENDITURES	ACTUAL				PROJECTED	
	FY 98/99	FY 99/00	FY 00/01	FY 01/02	FY 02/03	FY 03/04
Personnel Services	$2,527,121	$2,536,973	$3,003,626	$3,340,696	$371528741	$3,790,191
Operating Expenses	$3,338,539	$4,087,293	$3,762,807	$4,171,366	$4,016,126	$4,096,449
Total Expenditures	$5,865,660	$6,624,266	$6,766,433	$7,512,062	$7,732,000	$7,886,640
(-) Reimbursements	-$459,897	-$468,296	-$550,229	-$396,870	-$251,000	-$251,000
(-) Distributed Costs	$0	$0	$0	$0	$0	$0
Net Expenditures	**$5,405,763**	**$6,155,970**	**$6,216,205**	**$7,115,192**	**$7,481,000**	**$7,635,640**

Expenditures by Program Component

The board spends the greatest part of its budget on enforcement expenses. Over the last four years, more than 66 percent of the board's expenditures were spent on enforcement activities (when the 3 percent spent on the diversion program is included).

Table 12- Expenditures by Program Component

EXPENDITURES BY PROGRAM COMPONENT	FY 98-99	FY 99-00	FY 00-01	FY 01-02	AVERAGE % SPENT BY PROGRAM
Enforcement	$3,424,791	$3,881,995	$3,875,660	$4,610,617	63.4%
Examination	$263,431	$351,164	$351,964	$465,406	5.8%
Licensing	$934,947	$959,742	$863,318	$833,599	14.4%
Administrative	$682,127	$756,286	$944,535	$1,007,648	13.6%
Diversion	$100,467	$206,783	$180,726	$197,922	2.8%
TOTALS	**$5,405,763**	**$6,155,970**	**$6,216,205**	**$7,115,192**	

The board spent 24 percent on its licensing program. This includes nearly 6 percent of the board's budget that is related to examinations (both the pharmacist licensure examination and the exemptee exams, the latter were discontinued in July 2001).

The board's administration expenses comprise about 14 percent of its expenditures over the four years. The costs of the public education program are included in this category.

Fund Condition

The board is directed by the Business and Professions Code to seek to have a one-year reserve in its fund [section 4400(r)]. Over the last few years, the board's reserve has climbed as high as nearly 24 months due to the repayment of the money loaned to the General Fund in 1991/92. As such, the board reduced its fees in July 1999 to their lowest statutory levels for nearly all fees, deliberately creating a deficit between annual revenue generation and expenditures so that the amount of the reserve in the board's fund would decrease.

The proposed loan to the General Fund in 2002/03 of $6 million to help balance the state's budget will greatly reduce the board's reserve and trigger a need to increase fees in the immediate future (2003/04) unless the loan is repaid within one year. However, the board would have needed to increase fees in three years even without a transfer of a portion of its reserve simply because annual revenue is less than annual expenditures.

Over the last few years, the board has worked aggressively to propose and make program changes that will benefit the board's consumer protection mandate and improve operations. Key components in some of the proposals were budget change proposals to provide the necessary resources.

A list of budget change proposals prepared and submitted since the last sunset review is provided on the following pages. This lengthy list of proposals runs through all five of the board's policy committee areas and reflects a number of program refinements desired; most of these proposals were denied. For example, the denial of enforcement funding proposals limited the board's ability to investigate and close complaints timely especially during periods of high inspector vacancies caused by low salaries for board pharmacy inspectors (who are pharmacists). The denials also impacted the board's ability to pursue cases timely at the Attorney General's Office because the board's Attorney General funding was too low (and despite a high reserve in the board's fund). It took the board four-budget change proposals and four years to receive funding and one staff person for its public outreach program, despite the board's winning two national awards for its innovative program. The board's licensing processes have also been hampered by denial of requests for staff to process applications more timely or provide adequate review and audit control; these positions are needed to respond to a growing number of applicants and licensees over the years.

But the few budget change proposals that have been approved are critical factors in the board's success in reducing complaint closure time, establishing consumer outreach initiatives, publishing *Health Notes* monographs, pursuing a stronger legislative advocacy function and in tracking and managing enforcement functions to reduce investigation times.

Comparison of Revenues, Expenditures, and Reserves

Without a transfer of $6 million from the board's fund in 2002/03, the board's fund condition is:

Table 13 - Analysis of Fund Condition Without $6 Million Fund Transfer in 2002/03

ANALYSIS OF FUND CONDITION	FY 00/01	FY 01/02	FY 02/03 (Projected)	FY 03/04 (Projected)	FY 04/05 (Projected)	FY 05/06 (Projected)
Total Reserves, July 1	$11,247,623	$12,368,446	$10,810,963	$8,500,402	$6,024,827	$3,272,861
Total Rev. & Transfers	$7,387,675	$5,557,838	$5,170,438	$5,155,045	$5,031,266	$4,893,668
Total Resources	$18,635,299	$17,926,284	$15,981,402	$13,655,447	$11,056,093	$8,166,529
Total Expenditures	$6,214,634	$7,115,320	$7,481,000	$7,630,620	$7,783,232	$7,938,897
Reserve, June 30	$12,420,664	$10,180,963	$8,500,402	$6,024,827	$3,272,861	$227,632
MONTHS IN RESERVE	**24.0**	**18.2**	**13.6**	**9.5**	**5.0**	**0.3**

With a transfer of $6 million from the board's fund in 2002/03:

Table 14- Analysis of Fund Condition With $6 Million Fund Transfer in 2002/03

ANALYSIS OF FUND CONDITION	FY 00/01	FY 01/02	FY 02/03 (Projected)	FY 03/04 (Projected)	FY 04/05 (Projected)	FY 05/06 (Projected)
Total Reserves, July 1	$11,247,623	$12,368,446	$10,810,963	$2,500,402	($275,173)	($3,342,139)
Total Rev. & Transfers	$7,387,675	$5,557,838	($829,562)	$4,855,045	$4,716,266	$4,562,918
Total Resources	$18,635,299	$17,926,284	$9,981,402	$7,355,447	$4,441,093	$1,220,779
Total Expenditures	$6,214,634	$7,115,320	$7,481,000	$7,630,620	$7,783,232	$7,938,897
Reserve, June 30	$12,420,664	$10,810,963	$2,500,402	($275,173)	($3,342,139)	($6,718,118)
MONTHS IN RESERVE	**24.0**	**18.2**	**4.0**	**(0.4)**	**(5.2)**	**(10.2)**

If $6 million is transferred to the board's General Fund as part of the 2002/03 budget as currently proposed by the Budget Conference Committee, this will trigger a need for the board to increase fees in 2003/04 unless the loan is repaid early in fiscal year 2003/04.

BUDGET CHANGE PROPOSALS SUBMITTED VS. APPROVED
1997/98 TO 2002/03

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
1997/98	**Enforcement** Lease 21 vans for inspectors	$101,000			GOAL: To establish "offices on wheels" in vans so that inspectors could work or do undercover duties in board vehicles.
	Revised to 7 vans	$33,000	Purchased 7 vans	$245,000	During Administration negotiations, the board changed proposal to purchase vans over a four-year period.
1997/98	**Public Education** Fund 5-year public education program	$1,286,000 (for 5 years)	Denied		GOAL: Establish funding and one staff person for board public education and outreach; previously board members or redirected staff did this, which could not maintain effective program.
	Upon Appeal: Fund 2-year public education program with limited-term Associate Analyst (AGPA)	$263,000 first year $304,000 second year	1 AGPA - 2 year LT	$263,000 $304,000	Printing, postage, and travel. Printing, postage, and travel.
1998/99	**Enforcement** 4 Staff Services Analysts (3 field analysts and 1 subpoena analyst) 1 MST to do criminal background investigations 1 OA to support unit	$371,000	1 Subpoena Analyst 1 MST	$109,000	GOAL: Board sought analysts to assist hard-to-recruit inspectors in fieldwork, and specialized staff to collect and analyze court records and support enforcement staff.
1998/99	**Division of Investigation** 3,577 hours of investigation	$375,000	1,047 hours	$95,000	GOAL: To pursue egregious cases criminally; board inspectors lack peace officer status.
1998/99	**Licensing** 1 AGPA 1 MST	$168,000	1 AGPA 1 MST	$124,000	GOAL: To provide staff necessary to review and process site applications timely.

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
1998/99	**Public Education** 1 OA - Internet	$44,000	Denied		GOAL: To establish interactive feature on board's website, back-up the receptionist.
1999/00	**Licensing** Pharmacist Exam Job Analysis	$25,000	Approved (one time funding)	$25,000	GOAL: Conduct job analysis required for exam.
1999/00	**Public Education** Establish program permanently	$312,000	Approved (one year only, no staff)	$238,000	GOAL: To establish a public education program permanently staff with one designated staff person.
1999/00	**Legislation and Regulation** 1 Legislative Analyst	$75,000	Approved	$75,000	GOAL: Staff person to analyze legislation and do fiscal impact analysis.
1999/00	**Licensing** 1 OT - Change of Permit	$53,000	Denied		GOAL: Assure prompt processing of changes in site licenses.
1999/00	**Enforcement** 1 OT - Audit Entry	$53,000	Denied		GOAL: Establish specialized staff to enter pharmacy audit data; redirect inspectors to other duties.
1999/00	**Public Education** 1 OT - Customer Service	$53,000	Denied		GOAL: To establish an interactive feature on the board's web site, back-up receptionist.
1999/00	**Organizational Development** Training - AGPA and funding	$173,000	Denied		GOAL: Establish training budget and specialized staff to coordinate training of board staff.
1999/00	**Enforcement** AG Deficiency	$325,000	Denied		GOAL: Assure ongoing funding for AG services.
1999/00 2000/01	**Organizational Development** · Space Increase - One- time construction and rent · Rent Increase	$356,000 $146,000 (ongoing)	Approved	$146,000	GOAL: Provide funding for construction expenses and rent for expanded office space
2000/01	**Public Education** 1 AGPA, printing and expenses	$500,000	Partially Approved – No AGPA (absorb workload)	$238,000	GOAL: Permanently establish public education function and staff.

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
2000/01	**Organizational Development** Training - AGPA and funding	$125,000	Partially Approved – No AGPA	$45,000	GOAL: Provide ongoing training, budget and staff to integrate training for staff development and retention.
2000/01	**Enforcement** Legislative BCP (AB 1545) .5 Inspector	$75,000	.5 Inspector	$75,000	GOAL: Provide staff to perform inspections.
2000/01	**Enforcement** AG Deficiency	$383,000	Denied (current year augmentation denied)		GOAL: Assure ongoing funding for Attorney General Services. Major deficiency occurred in 2000/01 and a deficiency augmentation was required.
2001/02		$541,000	Approved – complete backlog of Attorney General cases	$541,000	
2002/03+ ongoing		$371,000	Approved but reduced	$135,000	
2000/01	**Enforcement** Deficiency Augmentation (Submitted 2/01)	$431,000	Approved 5/23/01 but reduced substantially	$143,000	GOAL: Continue Attorney General Services. Redirection from other budget items required; projects and purchases canceled; some AG casework suspended and delayed until next fiscal year.
2001/02	**Enforcement** Complaint Unit Augmentation 2 SSAs 1 OT	$189,000	Partially Approved 1 SSA	$60,000	GOAL: Faster resolution of consumer complaints. Establish as permanent three positions administratively created in January 2000 to deal with backlog of complaints.
2001/02	**Licensing** Site Licensing 2 OTs	$126,000	Denied		GOAL: Reduce processing times for exemptees and changes in site licenses.
2001/02	**Enforcement** Cite and Fine Program 1 SSA 1 OT	$134,000	Denied		GOAL: Linked with regulation to cite and fine for all violations. Regulations adopted within existing resources, reducing board's ability to implement regulation fully.

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
2001/02	**Public Education** 1 AGPA	$87,000	Denied Legislature added to the board's budget	$67,000	GOAL: Dedicate one position to coordinate education and outreach activities. Position added by Legislature during budget deliberations and approved in 2001/02 budget due to compelling need.
2001/02	**Licensing** Licenses to individuals 1 OT	$65,000	Denied		GOAL: Delays occurred in processing technician, intern, and foreign graduate applications, additional staff needed to handle workload expeditiously.
2001/02	**Organizational Development** 1 Staff Counsel	$119,000	Denied		GOAL: Board is a heavy user of legal advice; sought one attorney to handle board issues.
2001/02	**Legislation and Regulation** SB 1339 (Figueroa) Quality Assurance Program Newsletter – *Health Notes*	$100,000	Approved – one time		GOAL: Publish specialized monograph on establishing quality assurance program and reducing prescription error.
2001/02	**Legislation and Regulation** AB 2240 (Bates) Training and computer consultants for obtaining electronic prescription records	$40,000	Approved		GOAL: Provide specialized training in automation or technology consultants to download data from pharmaceutical computers.
2001/02	**Legislation and Regulation** SB 1828 (Speier) Internet Pharmacies 2 AGPAs 1 SSA 1 OT 2 Pharmacy Inspectors 0.5 Supervising Inspectors	$979,000	Denied		GOAL: Establish an aggressive a drug-buy program from the Internet and perform site inspections of Internet pharmacies in California annually.

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
2002/03	**Organizational Development** Budget Augmentation and Alignment to Underfunded Augmentations	$847,000	Approved: 1st Year Ongoing Printing (1st yr.) Printing (ongoing) Exam Site (ongoing) Contracts (ongoing) Travel (ongoing) Denied: Addt'l Printing (1st yr.) Addt'l Printing (ongoing) AG's Office Temporary Help Postage Proctors Overtime	 $261,000 $166,000 $159,776 $84,776 $41,600 $28,825 $10,800 $157,224 $232,224 $262,500 $109,000 $61,200 $13,900 $9,700	GOAL: Provide funding to 9 budget areas based on expenditures in prior years; areas funded by redirected salary savings from inspector positions.
2002/03	**Enforcement** Management Augmentation 2 Supervising Inspectors 1 OSS II 1 Chief of Enforcement	$525,000 (first year) $433,000 (ongoing)	Approved: $6,000 to upgrade one existing inspector position		GOAL: Correct insufficient span of control and management of board's enforcement program and office clerical staff.
2002/03	**Enforcement** Complaint Unit 1 SSA 1 OT	$135,000 (first year) $120,000 (ongoing)	Denied		GOAL: Hire specialized complaint resolution staff; reduce complaint processing times and create an 800 number for consumer calls.
2002/03	**Legislation and Regulation** SB 293 (Torlakson): Establish new licensing category of sterile compounding pharmacies 0.4 Supervising Inspector 2 Inspectors 1 MST 1 OT	$826,000 first year $608,000 ongoing	Partially funded	$75,000 first year $150,000 ongoing	GOAL: To provide staff to implement sterile compounding license; requires annual inspections. Board withdrew BCP for insufficiency as approved by Dept. of Finance (DOF); DOF then requests Finance Letter. Board withdrew BCP

Fiscal Year Effective	Requested		Approved		Comments
	Subject	Amount	Subject	Amount	
2002/03	**Legislation and Regulation** Finance Letter for SB 293 (Torlakson) Requested: 0.4 Supervising Inspector 2 Inspectors 1 MST 1 OT	$826,000 first year $608,000 ongoing	Partially approved 1 Supervising Inspector 1 Inspector 1 MST	$309,000 first year $272,000 ongoing	GOAL: To provide staff to implement sterile compounding license; requires annual inspections.
2002/03	**Legislation and Regulation** SB 644 (Sher): Requires any entity selling mercury thermometers to be licensed with the board as a hypodermic needle and syringe permit holder 10 OTs (Limited Term) 1 OSS II	$937,000 first year $212,000 ongoing	Denied		GOAL: Establish new licensure provisions for any entity selling mercury thermometers
2002/03	**Legislation and Regulation** SB 1169 (Alpert) Board required to produce informational material on the emergency contraception pill.	$11,000 one-time	Denied		GOAL: To develop and publish brochure on emergency contraception. Board must develop with existing resources but delay in producing brochure results.

LICENSURE REQUIREMENTS

Of the board's 12 major regulatory programs, four classes of licenses are issued to an individual to perform specific duties, the other eight are issued to facilities. For an individual's license, the applicant must satisfy certain educational and experience requirements established in statute and regulation. Because of the different scope of responsibilities for these four license classifications, the requirements differ greatly depending on the classification. The education and experience requirements for board licensees are listed below.

Table 15- Education, Experience, and Examination Requirements

EDUCATION, EXPERIENCE, AND EXAMINATION REQUIREMENTS	
License Class	**Requirements**
PHARMACIST	**Education**: Degree from a college of pharmacy or department of a university with 150 or more semester units of study and at least a Bachelor of Science degree in pharmacy, AND (see experience and examination) **Experience**: 1,500 hours of practical experience earned under the supervision of a pharmacist, AND **Examination Requirements**: Passage of the California Pharmacist Licensure Examination. Additionally, foreign educated pharmacists must first pass the written Foreign Pharmacist Graduate Equivalency Examination (administered by the National Association of Boards of Pharmacy) and the Test of Spoken English (administered by the Educational Testing Service) before being eligible to take the state licensure examination.
PHARMACIST INTERN	**Education**: Must be currently enrolled in an accredited school of pharmacy or have satisfied the education requirements specified to become a pharmacist. **Experience**: None **Examination Requirements**: None
PHARMACY TECHNICIAN	**Education**: A graduate of high school or a GED and either a minimum of an AA degree in health-related science or completion of a technician training program consisting of at least 240 hours of training, 120 must be in theory, OR (see experience) **Experience**: At least 1,500 hours of experience either working as a clerk typist in California or working as a pharmacy technician in another state or federal government. This experience must be earned under the direct supervision of a pharmacist. **Examination Requirements**: None
EXEMPTEE	**Education**: A graduate of high school or a GED and completion of training in five areas, or eligible to take the California pharmacist licensure examination, AND (see experience) **Experience**: One year paid experience in the distribution of prescription drugs or devices. **Examination Requirements**: None
EXEMPTEE – FOOD ANIMAL DRUG RETAILER	**Education**: A graduate of high school or a GED, completion of training in five areas, and specialized training for 240 hours, or registration as a veterinary technician being eligible to take the California pharmacist's or veterinarian's exams, or having worked 1,500 hours in a licensed veterinary retailer's premises, AND (see experience) **Experience:** One year paid experience in the distribution of prescription drugs or devices. **Examination Requirements:** None

VERIFICATION OF INFORMATION FROM APPLICATIONS

The board verifies information submitted on all applications before issuing a license, permit or registration. The method differs according to each program.

Some universal requirements include the submission of photographs, the submission of affidavits signed under penalty of perjury and the completion of fingerprint background checks. The photographs are used to confirm the identity of all applicants, the largest owners, highest officers, and designated managers. The affidavits are used to verify the information provided by the applicant on the application, typically for documenting experience and/or financial information. Federal and state fingerprint background checks are completed for all potential licensees and principal business owners and officers; this process is described in further detail below under Criminal History Information.

Candidates for the pharmacist licensure examination must submit the appropriate application and provide supporting documents demonstrating that they possess all requirements needed to take the examination. These documents include transcripts sent directly to the board's office from the school of pharmacy that display the degree earned and the date conferred, and proof of completion of the required intern hours submitted on affidavits completed by the supervising pharmacist. If the experience hours were earned in another state, verification of the intern hours must be submitted directly from the board of pharmacy in the state where the hours were earned. Alternatively, out-of-state license verification can be used to meet the experience requirements if the individual has prior experience earned as a pharmacist in another state. These supporting documents or affidavits must be sent directly from the agency or business to the board's office. Each applicant must submit signed and dated Rules of Professional Conduct. The board requires that applicants submit all supporting documentation, transcripts, etc., directly to the board from their originating sources to prevent fraud or misrepresentation. The board randomly verifies the licensure status of those signing affidavits.

Those seeking site licenses may be organized as a corporation, partnership, or individual business owner. The board requires the top five owners to submit notarized financial affidavits, which are scrutinized, to determine legitimate ownership and to prevent or discover hidden or prohibited ownership. The board accesses information from the Secretary of State to verify the legitimacy of corporations seeking to do business as a board licensee in California.

Criminal History Information

Included as part of each application are several questions that an applicant, individual or business owner or manager must answer and sign under penalty of perjury. The questions seek information on whether an individual has ever been convicted of or pled no contest to misdemeanor or felony charges, had prior disciplinary action taken by any regulatory board in this state or any other, if there has been any illegal use of controlled substances, and in the case of a pharmacist applicant, if the applicant ever been expelled from a licensure examination.

If an individual answers yes to any of the questions, the board requires a written explanation. If an individual responds no to any of these questions and the board later learns through the fingerprint verification process or via information from another regulatory board that the applicant has not been honest in responding, the applicant may be denied licensure. The applicant is asked to explain the circumstances and why the information was concealed.

If an applicant indicates a prior criminal conviction, the board requests copies of all pertinent arrest and court documents. For misdemeanors that are not drug-related, the board requests records for convictions up to three years old. For felonies and drug- related misdemeanors, the board requests records up to five years old.

Before the issuance of any license, a fingerprint background check is required from both the California Department of Justice and the Federal Bureau of Investigation. Prior to January 1, 2001, the board only required a background check from the California Department of Justice. This background check is required for every permit or registration issued to an individual. For site licenses, fingerprint background checks are required for the top five owners and officers as well as designated managers.

The board reviews the application and supporting documents. In addition to the fingerprint background check, the board completes checks on enforcement databases to confirm information provided on an application and to verify that no prior discipline has occurred. If prior discipline or past criminal information is revealed, the matter is referred to the board's enforcement unit for an application investigation.

The board may deny the application of any applicant for an individual or site license for acts substantially related to the functions or duties of the profession, occupation or business. The board reviews all of the documents submitted and collected, and analyzes whether the acts fit the criteria of California Code of Regulations, Section 1769 to make a decision whether a license or permit should be issued.

EXAMINATION INFORMATION

Of the board's 12 regulatory programs, only pharmacist applicants are required to take and pass a licensure examination. Prior to January 2002, the board also required an examination of applicants for an exemptee license. Effective January 1, 2002, an examination is no longer required; instead, applicants must qualify based upon specific experience and training (SB 724, Senate Business and Professions Committee, Chapter 728, Statutes of 2001).

Table 16 - California Pharmacist Licensure Exam

CALIFORNIA PHARMACIST LICENSURE EXAMINATION		
Fiscal Year	Total Candidates	Passage Rate
1998/99	1,458	51%
1999/00	1,602	53%
2000/01	1,756	55%
2001/02	1,692	53%
Overall	6,508	53%

The pharmacist license examination is required to demonstrate a minimum competency to practice as a pharmacist in California. The actions of an unqualified pharmacist could result in serious patient harm, including death.

Currently the board administers its own exam twice a year; however, California is the only state that does not use the North American Pharmacist Licensure Examination (NAPLEX) to test minimum competency.

The board's licensure examination tests candidates for competency in tasks that are the practice of pharmacy. Whereas education programs are designed to ensure that individuals possess the underlying knowledge for entry into the profession, there is no examination at the completion of the academic program that tests individuals on their cumulative knowledge base needed by pharmacists. This is the purpose of both the state's and the national exams.

Job Analysis for the California Pharmacist Examination

Every five years the board conducts a job analysis of pharmacists to identify elements of practice. (A copy of the last analysis is available from the board.) To conduct a job analysis, a sample of pharmacists is surveyed to determine the tasks that pharmacists perform, how frequently they perform the tasks, and the importance that professionals in the practice assign to these tasks. The results are used to create a content outline for the development of the pharmacist licensure examination, prioritizing the tasks performed by pharmacists. The number of questions related to each competency area is determined by the relative importance assigned to the tasks by the pharmacists who participated in the job analysis

The last job analysis was initiated in late 1999, with a report completed in April 2000. The job analysis was conducted by the board's psychometric consultant. The result of this job analysis was first reflected in the June 2001 licensure examination.

The board provides candidates with the current outline from which the examination is constructed as part of its application information and publishes it in the *Candidate's Review Guid*e, which is provided at no cost to candidates and is available to download from the board's website. The guide also contains retired examination questions and answers to aid applicants in studying for the exam.

Application Processing Times

The board issues a diversity of permits to individuals and to premises. All licensees require separate and in several cases complex applications, reflecting the complexity of the state's regulation of those who distribute prescription drugs and devices to the public and to other practitioners. The processing times for these permits are listed below, and reflect the board's balance of the need to closely review an application before issuing a permit, and the applicant's desire to enter commerce or practice immediately. Nevertheless, the board will not issue a permit until the application is complete, all requirements fulfilled, and review of the application

is completed. In cases where the applicant lacks the requirements or does not supply the information, the license is denied. Some applicants withdraw their applications during the process for a variety of reasons, sometimes because of their criminal convictions. The board may withdraw other applications if the applicant fails to correct deficiencies in 60 days after being advised about the deficiency, and the applicant abandons the application.

In 1996, the board altered its applications for site licenses to collect greater detail about ownership of the premises, prior convictions and disciplinary actions of owners and corporate officers by other regulatory boards in the United States. In 2001, the board began requiring of all applicants, owners and officers, fingerprint clearances from the Federal Bureau of Investigation in addition to clearances from the California Department of Justice. Simultaneously, the California Department of Justice implemented Live Scan (electronic submission of fingerprints rather than on cards) as the preferred mode of submission of fingerprints. These changes impacted the board's processing times for applications since the processing of applications is most greatly affected by the time required to obtain federal and state fingerprint clearances, which are processes beyond the board's control.

Generally, fingerprint clearances are currently received in four weeks. Those who have criminal convictions take longer for reports from the Department of Justice or FBI, sometimes three or four months. In these cases, the board needs the specific conviction documents as well. Applicants whose fingerprints are not clear enough to read must resubmit them, which also extends the processing time for any application.

Table 17 - Average Number of Days to Process an Application

AVERAGE NUMBER OF DAYS TO PROCESS AN APPLICATION *		
Application Type	**Without Deficiencies**	**With Deficiencies**
Clinic	50	124
Exempt Hospital Pharmacy	82	191
Exemptee	6**	24**
Hospital	71	172
Hypodermic Needle	26	162
Intern	37	59
Licensed Correction Facility	20	88
Non Resident Pharmacy	113	275
Pharmacy Technicians	63	98
Pharmacy	41	80
Out of State Distributor	57	216
Veterinary Food-Animal Drug Retailer	54	341
Wholesaler	50	212

* Average processing times are based on a random sample of applications processed throughout the year.
**Averages for January 1, 2002 through April 30, 2002, based on new statutory requirements.

Statutory requirements for licensees determine the application process and information requested. For example, substantial structural changes in the method by which wholesaler exemptees qualify for licensure were made in 2001 legislation, which triggered changes in the application and board review of qualifications for these applicants. It also simplified the process in that an examination was no longer required, which reduced processing time for an exemptee license. Additionally, the board established master files for facilities with multiple locations to reduce the number of documents that must be submitted as part of a facility license.

Additionally the applicants for site applications have themselves changed over the years. Increasingly, applicants for wholesaler and pharmacy licenses are corporate owners, sometimes comprised of multiple corporate layers of ownership. For such applicants, the application is more complex because information about each layer is collected and analyzed.

The pharmacist licensure examination is developed by the board and given twice a year on preset dates. Board regulations establish deadlines for submission of applications (60 days before the exam) and correction of deficiencies for this exam (30 days before the exam); however, the board has been able to accommodate those who submit applications or correct deficiencies after the deadlines.

Once the results of the examination are released – typically eight to ten weeks after exam administration — pharmacist applicants who have fulfilled all license requirements are issued pharmacist licenses as quickly as possible; the performance standard is within three business days, but the board is generally even faster than three days. Additional staff is assigned to assist in this process to assure the nearly immediate processing of pharmacist licenses to those who fulfill all requirements. The board does this in recognition of the pharmacist shortage and the need for employers to hire these new pharmacists.

Table 18 - Average Number of Days to Process Change of Permits

AVERAGE NUMBER OF DAYS TO PROCESS CHANGE OF PERMITS *		
Permit Type	**Without Deficiencies**	**With Deficiencies**
Clinics	26	27
Exempt hospital pharmacy	27	151
Hospital Pharmacy	17	23
Licensed Correctional Facility	25	25
Non-Resident Pharmacy	20	21
Community Pharmacy	14	17
Hypodermic Needle & Syringe	none received	none received
Out of State Distributor	51	72
Veterinary Food Animal Drug Retailer	none received	none received
Wholesaler	26	26

* Change of Permit applications must be submitted when there is less than a 50 percent change in ownership of a facility, when new corporate officers are appointed/elected, or a change of corporate name.

However, for those who pass the examination but still have deficiencies in their qualifications to become licensed as a pharmacist (for example, missing some or all of the additional 500 of the 1,500 hours of intern experience needed, licensure verification from another state in which they are licensed), the board notifies these individuals of their deficiencies and makes every effort to license them as quickly as possible after their deficiencies are resolved.

Over the past six years, the board has expanded its application processing staff through budget augmentations to reduce processing times, reduce workload backlogs and provide more thorough review of applications. However, not all staff requested through the budget change proposal process has been approved. Additionally, the number of board applicants has increased further straining processing time. The result is less than ideal processing times for applications, and not all applications being handled as timely as others since the board must prioritize its processing workload.

The overall average processing time for pharmacy site applications submitted as complete applications (no deficiencies) had been 48 days in 1996; today it is 41 days. This is a 15 percent reduction in processing time.

For pharmacy applications that are deficient, the total processing time had been between 65 and 112 days (depending upon the type of deficiency) in 1996. Today, the average processing time for an application submitted with deficiencies is 80 days (this can be viewed as the processing time applicants can expect from the date the application is submitted until the permit is issued).

Table 19 – Average Number of Days to Process Change of Pharmacist-in-Charge

AVERAGE NUMBER OF DAYS TO PROCESS CHANGE OF PHARMACIST-IN-CHARGE		
Permit Type	**Without Deficiencies**	**With Deficiencies**
Hospital Pharmacy	15	27
Licensed Correctional Facility	13	19
NonResident Pharmacy	16	18
Community Pharmacy	14	23

One of the primary reasons for the reduction in processing time is that the board has developed specialized office staff to review and approve applications, whereas the last sunset review, the board's field inspectors of pharmacists approved the applications for sites.

Some of the causes for longer average processing times involve applicants who are out of state who must submit fingerprint cards, which take longer to process than do prints submitted under Live Scan. This processing time by the Department of Justice and FBI is not counted as deficient time by the board, thus the overall average processing time is longer for those submitting fingerprints on cards as part of their application.

The board has been able to offset insufficient numbers of licensing staff to some degree with the use of technology. The board's automated telephone system provides applicants with information once only available from staff, and applications can be requested via a message system. Additionally the board's website has information about applications and the applications themselves can be downloaded. Use of the licensure verification screens helps applicants learn within 24 hours of when a license has been issued to them, faster than receiving the license in the mail.

The state's hiring freeze has also greatly impacted the board's processing of applications. For example, during peak processing times for the pharmacist licensure exam, additional staff is needed because of the workload surge caused by the processing deadlines. Currently the board has vacancies in two positions that process or assist in processing applications, and these vacant positions have made it difficult to provide the level of client service the board would prefer. As a result, staff principally spends their time processing applications and responds to status requests from applicants whose applications have been submitted for a period of time. Unless the board does this, considerable application processing time would be lost. This is not a desired level of service the board wishes to provide to our applicants but at current staffing levels is unavoidable.

Continuing Education/Competency Requirements

Pharmacists are the only board licensees required to earn continuing education (CE) to renew their licenses. The CE requirements for pharmacists have not changed since the last sunset report. As part of the renewal process for every pharmacist, he or she must certify completion of the required 30 units of CE during the two-year renewal period.

The CE earned by a pharmacist must be related to health care including: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, public health and communicable disease, professional practice management and anatomy.

Currently, the board accepts courses that are accredited by the American Council on Pharmaceutical Education (ACPE) or Accreditation Evaluation Services (AES). The board also permits providers to petition the board for approval of a course. Additionally, pharmacists may petition for credit for courses completed in health-related areas. To decrease the need for a pharmacist to petition for credit for such courses, the board has directed staff to move forward with a regulation change that would allow credit for health-related coursework approved by other health licensing boards, e.g., Board of Registered Nursing or California Medical Board.

The board also provides pharmacists with the opportunity to earn some CE credit through board-published monographs; the development of these monographs ensures that pharmacists are presented with knowledge the board considers essential to pharmacists' care. In the future, the board plans to host board-sponsored CE seminars on pharmacy law, which is consistent with one of the Enforcement Committee objectives.

Comity/Reciprocity with Other States

Currently, pharmacists seeking to practice in California must take the California licensing examination offered by the board. That examination is offered twice each year (January and June). There is no provision for the issuance of a temporary license to practice as a pharmacist. Pharmacists licensed in other states may obtain a pharmacist intern permit or even a pharmacy technician permit to work under the supervision of a California-licensed pharmacist in California until they can take and pass the California exam. However, the scope of duties for interns or technicians is limited from that of a pharmacist.

Foreign graduates of pharmacy schools may qualify to take the board's pharmacist exam after they demonstrate the equivalence of their education to that of domestic pharmacy school graduates. They do this by passing the Foreign Pharmacist Graduate Equivalency Exam (administered by the National Association of Boards of Pharmacy), at which point they can obtain an intern permit and gain the experience in California pharmacies which is needed before they can take California's exam

All other states use the North American Pharmacist Licensure Examination (NAPLEX) as the primary measure of minimum competency for pharmacists, which make it comparatively simple to obtain licensure in other states. The NAPLEX is a computer adaptive exam, offered at a number of locations nationally most workdays throughout the year. *(The use of the NAPLEX examination is discussed in the Overview section of this report under the Licensing Committee.)*

ENFORCEMENT PROGRAM OVERVIEW

The Board of Pharmacy is responsible for enforcing a complex network of federal and state laws pertaining to the acquiring, storing, distributing and dispensing of prescription drugs and devices. The board regulates designated individuals who perform services in this area and designated facilities that perform these services. The board's enforcement program exists to ensure the protection of the public and is *the* key area of board activities.

The board allocates the greatest amount of staffing and operating resources to this program area, and has greatly expanded its activities here since the last sunset review. Enforcement is achieved through voluntary compliance, education, intermediate sanctions (citations and fines) and administrative actions, and is accomplished through a combination of investigation and inspection activities. These activities are described in this section in response to the Sunset Review Committee's questions.

If an investigation reveals substantial pharmacy law violations, the matter may be referred to the Office of the Attorney General for action. Disciplinary penalties include interim suspension orders, license revocation, voluntary license surrender, suspension and probation. And for the most serious violations, criminal prosecution may be pursued.

For less serious offenses, the board uses alternative methods to educate pharmacists and other licensees and bring them into compliance. An essential component of the board's enforcement program is voluntary compliance with pharmacy law pursued through routine, unannounced inspections of licensed sites by the board's pharmacy inspectors. The general scope of the board's inspection program is prevention through education -- informing pharmacists about legal requirements and standards of practice. Among the enforcement tools used by the board during inspections are written correction orders, verbal instructions, and notices of violation that can result in a citation or a citation and fine. These methods are pursued when the violations are minor and technical in nature, and not serious enough to warrant referral to the Attorney General's Office.

The board also has a Pharmacists Recovery Program to speed entry into rehabilitation and monitoring of those with substance abuse or mental impairment problems, while the board continues its investigation of the individuals.

The table on the following page displays data describing the outcome of a number of board enforcement activities requested in the sunset review survey.

Complaints Received

The investigation process typically starts with a complaint. The board receives complaints from a number of sources; the greatest number of complaints are from the public.

The board received 5,205 complaints during the last four years, 153 percent of the 3,399 complaints received during 1992/93 through 1996/97.

Table 20 – Enforcement Activity

ENFORCEMENT ACTIVITY								
Activity	**FY 98/99**		**FY 99/00**		**FY 00/01**		**FY 01/02**	
Inquiries:	Total:	**178,978**	Total:	**315,978**	Total:	**760,820**	Total:	**1,593,873**
Telephone		178,596		114,311		84,882		83,045
Written Correspondence		382		356		244		546
Web Site Hits		n/a		201,311		675,694		1,510,282
Complaints Received (By Source)	Total:	**1,075**	Total:	**1,299**	Total:	**1,198**	Total:	**1,633**
Public		588		588		572		618
Licensee/Professional Groups		172		208		175		236
Governmental Agencies and Law Enforcement		222		375		223		230
Other (Internal, 802, and misc.)		93		128		228		549
Complaints Filed (By Type)	Total:	**1,075**	Total:	**1,299**	Total:	**1,198**	Total:	**1,633**
Competence/Negligence		314		365		330		481
Unprofessional Conduct		236		224		222		220
Fraud		8		16		6		16
Health & Safety		169		185		213		389
Unlicensed Activity		147		190		199		275
Personal Conduct		125		255		137		158
Other (non-jurisdictional & other)		76		64		91		94
All Complaints Closed	Total:	**1,050**	Total:	**1,038**	Total:	**1,879**	Total:	**1,905**
Application Investigations Closed	Total:	**623**	Total:	**627**	Total:	**693**	Total:	**595**
Investigations & Mediations Commenced	Total:	**979**	Total:	**1,116**	Total:	**983**	Total:	**1,555**
Application Investigations Commenced	Total:	**569**	Total:	**566**	Total:	**627**	Total:	**594**
Compliance Actions Completed	Total:	**389**	Total:	**381**	Total:	**849**	Total:	**904**
ISOs & TROs Issued		1		0		4		3
Citations and Fines		112		32		90		206
Public Letter of Reprimand		227		282		658		620
Cease & Desist/Warning		40		59		65		40
Referred for Diversion		8		5		27		25
Compel Examination		0		0		1		3
PC 23		1		3		4		7
Referred for Criminal Action	Total:	**0**	Total:	**0**	Total:	**1**	Total:	**1**
Referred to AG's Office	Total:	**149**	Total:	**91**	Total:	**105**	Total:	**148**
Accusations Filed *	Total:	**64**	Total:	**107**	Total:	**73**	Total:	**147**
Accusations / Statement of Issues, Withdrawn or Dismissed	Total:	**29**	Total:	**64**	Total:	**29**	Total:	**56**
Stipulated Settlements	Total:	**51**	Total:	**57**	Total:	**100**	Total:	**108**
Proposed Decisions	Total:	**27**	Total:	**17**	Total:	**17**	Total:	**28**
Default Decisions	Total:	**12**	Total:	**15**	Total:	**25**	Total:	**46**
Disciplinary Actions *	Total:	**84**	Total:	**89**	Total:	**142**	Total:	**182**
Revocation		21		30		44		64
Voluntary Surrender		5		11		12		15
Suspension Only		0		3		3		1
Probation with Suspension		23		17		22		9
Probation only		25		19		38		57
Probationary License Issued		3		4		4		2
Reprimand		7		2		15		29
License Denied		6		3		4		5
Probation Violations	Total:	**0**	Total:	**0**	Total:	**0**	Total:	**2**
Suspension or Probation		0		0		0		0
Revocation or Surrender		0		0		0		2

* When the board files an accusation, the accusation may name multiple respondents (the pharmacy, the pharmacist-in-charge, other pharmacists, and pharmacy technicians); however, only one accusation is counted for all of these respondents. When an accusation is withdrawn, it may be withdrawn against one or more respondents, but administrative action will continue against the other respondents. The disciplinary action data reports actions taken against permits and so will exceed the number of accusations filed.

Consumers submitted 45 percent of the complaints received in the last four years, whereas 51 percent of the complaints during the prior sunset review period were from consumers. Government/law enforcement agencies are the origin of 20 percent of the board's complaints during the last four years; these comprised only 13 percent of the origin of the board's complaints previously. These complaints are typically notifications of criminal arrests or convictions by law enforcement agencies.

COMPLAINTS RECEIVED BY SOURCE	FY 1992/93 through FY 1996/97		FY 1998/99 through FY 2001/02	
Public	1,744	(51.3%)	2,366	(45.4%)
Licensee / Professional / Association	561	(16.5%)	791	(15.9%)
Governmental Agencies and Law Enforcement	433	(12.7%)	1,050	(20.2%)
Other (Internal, 802 and miscellaneous)	661	(19.4%)	998	(19.2%)
Total Complaints Received	3,399	(99.9%)	5,205	(100%)

Table 21 - Complaints Received

The "other" category of complaint origin includes cases opened by board inspectors during routine inspections, as well as truly miscellaneous sources of complaints. During both time periods, this source was the origin of 19 percent of the board's complaints.

There are multiple reporting mandates to inform the board about possible matters for investigation:

- ***Business and Professions Code Section 802*** - Board licensees or their legal representatives are required to report every settlement or arbitration award over $3,000 due to a "claim or action for damages for death or personal injury caused by negligence, error or omission in practice." The board receives notification of these settlements from the insurance company settling the claim or from a licensee's counsel.
- ***California Code of Regulations Section 1715.6*** – Requires an owner to report to the board within 30 days of discovery the loss of any controlled substances, including their amounts and strengths.
- ***California Code of Regulations Section 1715.5*** - The Controlled Substances Utilization Review and Evaluation System (CURES) tracks outpatient prescriptions dispensed in California for all Schedule II drugs. Each month pharmacies transfer computer files to the Department of Justice (DOJ) detailing all Schedule II prescriptions dispensed by the pharmacy.
- ***California Code of Regulations, Section 1742*** – Requires drug wholesalers to report to the board sales of dangerous drugs subject to abuse on a periodic basis, as directed by the board. Although staff shortages have prevented the board from pursuing this data in recent years, in June 2002 the board hired a staff person specifically to perform this function and oversee CURES data as a means to initiate investigations.

There are no statutory requirements for licensees to report to the board unprofessional conduct or violations of pharmacy law by themselves or other licensees. However, statutory requirements do exist that a licensee take appropriate action and have specific procedures in place to protect the public:

- ***Business and Professions Code, Section 4104*** – Mandates that pharmacies have procedures for taking action to protect the public when a licensee employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice pharmacy. The pharmacy must also have procedures for taking action to protect the public when a board licensed employee is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy.

- ***Business and Professions Code, Section 4125 and also California Code of Regulations, Section 1711***– Requires all pharmacies to develop quality assurance programs to study and evaluate prescription errors to assess the cause and any contributing factors to the medication error and prevent recurrence of such errors.
  A record of the quality assurance review shall be immediately retrievable in the pharmacy and include specific data including any recommended changes to pharmacy policy, procedure, systems or processes.

- ***California Code of Regulations, Section 1715***– Requires that the pharmacist-in-charge of a pharmacy complete a self-assessment of the pharmacy's compliance with state and federal pharmacy law. The board develops and provides the self-assessment forms to educate pharmacists on the requirements of pharmacy law, to seek voluntary compliance and self-monitoring of their pharmacy practice. This self-assessment must be completed every two years or whenever the pharmacist-in-charge changes.

Also, through a mandate of the U.S. Department of Health and Human Services, the board provides disciplinary information to the Healthcare Integrity and Protection Databank (HIPDB). The HIPDB is a national health care fraud and abuse data collection program for the reporting and disclosure to certain final adverse (disciplinary penalty) actions taken against health care providers, suppliers, or practitioners. Information reported to the HIPDB is available to federal and state government agencies, health plans, and via a self-query for health care providers, practitioners, and suppliers.

City and county law enforcement officers, probation officers, district attorneys and federal agents routinely contact the board concerning the arrests and/or probation violations of the board's licensees. This sharing of information allows the board to move quickly in determining the most appropriate and expeditious disciplinary action to ensure public protection. The board uses the provisions of Penal Code section 23 to seek restrictions on the ability of a licensee to practice pharmacy.

Penal Code section 23 provides that in any criminal proceeding against a person who has been issued a license to engage in a business or profession under provisions of the Business and Professions Code, the state agency that issued the license may appear during any criminal proceeding to furnish information or make recommendations regarding specific conditions of probation necessary to protect the interests of the public. Penal Code section 23 grants the court the ability to prohibit the licensee to practice his or her profession either during the reminder of the criminal proceedings, as a condition or probation, until the disciplinary action is completed by the board or as otherwise determined by the court.

In the last two years, the Attorney General's Office, on behalf of the board, made eight criminal court appearances to request Penal Code section 23 practice restrictions on licensees. The board was successful in seven of these hearings, resulting in an immediate cessation of the licensee's ability to practice either pending the outcome of the criminal matter or until completion of the board's administrative case. Such egregious violations warrant swift action.

The board also uses the provisions of section 4311 of the Business and Professions Code to automatically suspend a license during any time a licensee is incarcerated after a felony conviction. This section also authorizes the board to summarily suspend a license depending on a combination of factors: the type of criminal conviction; whether the offense was committed in the course of business or practice for which the license was issued; whether committed in a manner in which the patient/customer was a victim; if the specific intent was to deceive, defraud, steal, or make a false statement; the illegal possession for sale or trafficking of a controlled substance; and whether the felony conviction is substantially related to the qualifications, duties or functions of a licensee. In the last two years, the board was able to use this authority to suspend two licenses pending the completion of the corresponding disciplinary case.

The board has few problems with receiving complaint information or obtaining information for investigation purposes. In the last four fiscal years, approximately 20.2 percent (1,050) of the complaints received were reported to the board from licensees, other government agencies, and local law enforcement agencies. Board enforcement staff can clarify facts provided or obtain additional information from the referring agency. In conducting criminal conviction investigations, the board has little difficulty in retrieving sufficient arrest and court documentation from law enforcement agencies and state and federal courts. Typically, documentation (such as certified court and arrest records, confirmation of criminal probation status, and any outstanding arrest warrants) is readily provided to the board upon request.

Additionally, even if the police departments or courts don't notify the board about a licensee's arrest and conviction, the Department of Justice does notify the board once a fingerprint match is made by the DOJ's fingerprint system. The exception to this notification occurs with arrests where only driving under the influence is charged (according to the Department of Justice, there are too many of these matches in the state's computer records to notify all agencies).

In the last four fiscal years, the board received a yearly average of 1,300 complaints that resulted in either an investigation or mediation. Mediations are generally handled by the board's enforcement analysts. Investigations are handled by one of the board's inspector teams. An investigation or mediation is initiated when a complaint or information is received that alleges illegal practices.

The majority of the complaints filed with the board involve quality of care issues such as prescription errors. These complaints are categorized as negligence/incompetence and include allegations of incorrect medication dispensed, prescription labeling errors, variation from the requirements of a prescription, generic substitution and patient counseling violations. Of the 5,205 complaints received from 1998/99 through 2001/02, 28.6 percent (1,490) were for this category.

Table 22 - Complaints Received By Type

COMPLAINTS RECEIVED BY TYPE	FY 1992/93 through FY 1996/97		FY 1998/99 through FY 2001/02	
Competence/Negligence	111	(3.3%)	1,490	(28.6%)
Unprofessional Conduct	887	(26.1%)	902	(17.3%)
Fraud	48	(1.4%)	46	(0.9%)
Health and Safety	1,187	(34.9%)	956	(18.4%)
Unlicensed Activity	366	(10.8%)	811	(15.6%)
Personal Conduct	216	(6.4%)	675	(13.0%)
Other (includes non-jurisdictional)	584	(17.2%)	325	(6.2%)
Total Complaints Received	3,399	(100.1%)	5,205	(100%)

The second largest category of complaints alleges unprofessional conduct (17 percent of the 5,205 complaints received). Unprofessional conduct complaints involve such violations as unethical practices, failure to release records or breaches of patient confidentiality. Unprofessional conduct can include general violations of pharmacy law, records violations, violations of disciplinary probation and drug quality issues.

Unlicensed or unregistered performance of pharmacy-related services account for 15.6 percent of the board's complaints in the last four years, compared to 10.8 percent for fiscal years 1992/93 through 1995/96.

The board received 1,292 prescription errors complaints in the last four years, 46 percent more than the 883 prescription error complaints received during 1992/93-1996/97. In light of the rising trend of prescription error complaints and to advocate for better pharmacists' care, the board sponsored legislation and promulgated implementing regulations that became effective in January 2002 requiring all pharmacies to develop quality assurance programs to study and evaluate medication errors to prevent the recurrence of the errors. The board's goal for quality assurance programs is to reduce the frequency of medication errors through the documentation and systematic study of those errors.

Investigation of Complaints

The board initiates an investigation when a complaint or information is received that alleges illegal practices. In addition to investigating complaints submitted to the board, internal or board-originated investigations are conducted as a result of information obtained from routine inspections, receipt of criminal conviction information, and applications for licensure.

The purpose of an investigation is to determine whether state or federal pharmacy laws have been violated. This is done by an inspector, with oversight and direction provided by a supervising inspector. The supervising inspector reviews all complaints, investigations and mediations, determines the appropriate assignment, and performs a preliminary case assessment.

The inspector gathers the evidence, makes preliminary conclusions about violations of laws and regulations, which the evidence may substantiate, and records the findings in an investigation report.

Investigations are prioritized based upon the type of violations involved, such as drug abuse, drug diversion, patient harm, and criminal convictions. Complaints categorized as priority one and two investigations are the most serious and include reports of an impaired pharmacist on duty, reports of prescription drug theft by a pharmacist, no pharmacist on duty, controlled substance shortages, and unauthorized furnishing of prescription drugs and/or controlled substances. Priority one and two complaints are those complaints that could, depending on the severity and number of violations involved, ultimately be referred to the Attorney General's Office for disciplinary action. Accusations are filed in these serious cases and the board pursues the appropriate disciplinary penalty, either through the administrative hearing process or through a stipulated settlement.

The board has also developed a team of non-pharmacist complaint specialists who mediate consumer complaints when an investigation is not needed. As before these staff work closely with a supervising inspector to mediate a complaint, and the supervising inspector reviews and recommends actions based upon the mediation's findings.

The board has other enforcement sanctions it can use for lesser violations of pharmacy law under authority provided for in board regulations. For years, a committee of the board could cite and fine licensees for failing to provide patient consultation about new prescription medications. Additionally, the board could cite and fine for unlicensed activity, and in 2000, could cite and fine for failure to earn continuing education credits. Until July 2001, this was the limit to the board's ability to cite and fine.

In a process implemented since April 2002, the board's Citation and Fine Committee now may review enforcement cases and assess a citation with or without a fine, pursuant to board regulations that took effect in mid 2001. These regulations allow the board to cite and fine for any violation of pharmacy law. The Citation and Fine Committee replaced the board's Compliance Committees, which had existed for years.

Stipulation of Cases

Any enforcement case referred to the Attorney General's Office may be settled via a stipulated settlement after an accusation is filed. The board's *Disciplinary Guidelines* is an important reference to determining standard (or acceptable) terms. Typically, the respondent will offer terms for settlement, but the board can also offer terms.

In determining settlement terms, the executive officer reviews the background and history of the case and of the responsible licensees, and considers all aspects of the investigation, including any mitigating circumstances and then refers to the board's *Disciplinary Guidelines* for the appropriate category of violation and corresponding minimum and maximum penalties.

Negotiations during settlement typically involve the seriousness of the charges, the volume and scope of the charges, how recent the charges are, the intent of the respondent, the respondent's evidence of mitigation or rehabilitation, or evidence that some of the charges are unfounded.

The final – and most important – factor when negotiating disciplinary penalties is the protection of the public. This includes consideration of whether the respondent can practice pharmacy or operate a pharmacy safely. If not, revocation or surrender of the permit may be a required term to settle the matter either with or without the monitoring and restrictions that disciplinary penalties imposed.

At the time of the last sunset review, the board agreed to resolve 207 disciplinary penalties through stipulations. In the last four fiscal years, the board approved 316 penalties through the settlement process. There have been no changes in the negotiation process or the factors to be considered in determining an appropriate case for settlement.

The board updated its *Disciplinary Guidelines* to conform with the 1997 legislation reorganizing pharmacy law and promulgated section 1760, California Code of Regulations, adopting the board's guidelines as regulations. More recently, the board again revised the guidelines and the current version has been in effect since November 2001

Complaint Referrals for Investigation and Disciplinary Action

From 1998/99 through 2001/02 the board received a growing number of complaints that reached over 1,630 in 2001/02; 152 percent of the complaints it received in 1998/99 *(see Table 23 on the next page).*

The board mediates or investigates all complaints. Mediations are used for complaints that are less technical in nature and are routinely handled in-house by board analysts but can also be referred to the board's pharmacy inspector Compliance Team for mediation if an inspection of the pharmacy is warranted. Complaints that are more technical and serious in nature, indicating a potential for patient harm, are investigated by one of the board's pharmacy inspector teams – Compliance, Drug Diversion, or Pharmacists Recovery Program/Probation.

The board also investigates those applications wherein the applicant stated that he or she had been convicted of a crime or when a fingerprint background check of an applicant resulted in criminal information being received from the Department of Justice. In these cases, supporting arrest and conviction documentation is obtained and analyzed to determine whether a permit should be issued or denied under the authority of the Business and Professions Code section 480.

An application investigation is also initiated when a review of the application indicates prior disciplinary action, disciplinary action is pending or out-of-state disciplinary action has occurred against the applicant and/or applicants; when there is a question of prescriber ownership of a pharmacy or when the board has a concern with any of the supporting application documents, such as financial or corporate affidavits.

Since 1998/99 the board has initiated 2,356 application investigations; an average of 589 investigations each year. The board closed 2,538 application investigations over the last four fiscal years, which is a sizable but important workload.

At the time of the last sunset review, 16 percent of all complaints received during that reporting period were mediated and 84 percent were investigated. Since 1998/99, 29 percent of the complaints closed have been mediated and 71 percent have been investigated.

Since 1998/99, the board has referred 493 cases to the Attorney General's Office (an average of 123 cases per year) and filed 391 accusations. Since 1998/99 the board has levied 495 disciplinary sanctions ranging from probation to revocation on licensees – a 48 percent increase since the last reporting period. Because of the inherent time required to discipline a licensee, additional enforcement sanctions will ultimately be taken against those with enforcement cases currently pending.

Table 23 – Number and Percentage of Complaints Dismissed, Referred for Investigation, to Accusation, and for Disciplinary Action.

NUMBER AND PERCENTAGE OF COMPLAINTS DISMISSED, REFERRED FOR INVESTIGATION, TO ACCUSATION AND FOR DISCIPLINARY ACTION								
	FY 98/99		FY 99/00		FY 00/01		FY 01/02	
Complaints Received	1,075		1,299		1,198		1,633	
Closed, Non Jurisdictional	96	(9%)	183	(14%)	215	(18%	78	(5%)
Referred for Investigation	979	(91%)	1,116	(86%)	983	(82%)	1,555	(95%)
Accusations Filed	55	(6%)	53	(5%)	63	(6%)	26	(0.2%)
Disciplinary Action *	41	(4%)	33	(3%)	34	(3%)	6	(0.4%)

* Data reflects those complaints received in a specific fiscal year that resulted in subsequent disciplinary action. This number does not include those disciplinary cases that are still pending or the total number of disciplinary penalties received. Additional disciplinary action is pending and will be taken in the future against some of these complaints.

Case Aging Data

Since the board's last sunset review, the board's processing time to complete investigations and enforcement actions skyrocketed, and then over the last two years just as quickly and substantially decreased. This processing time is directly linked to the number of trained staff available to the board to mediate, investigate and manage board enforcement activities.

Today the board generally meets its performance standards of investigating or mediating complaints in 90 days and completing all complex investigations within 180 days. This is a significant achievement, made more notable because the board's complaints have increased 52 percent from 1998/99 to 2001/02.

Table 24 – Average Days to Process Application Investigations, Complaints, Investigate and Prosecute Cases

AVERAGE DAYS TO PROCESS APPLICATION INVESTIGATIONS, COMPLAINTS, INVESTIGATE AND PROSECUTE CASES				
	FY 98/99	FY 99/00	FY 00/01	FY 01/02
Application Investigations	166	125	114	80
Complaint Processing (Mediations)	493	339	272	91
Investigations	390	404	303	83
Referral to the Attorney General	98	122	154	181
Pre-Accusation *	308	242	305	188
Post-Accusation **	490	369	403	395
TOTAL AVERAGE DAYS ***	1,286	1,137	1,165	847

***** From completed investigation to formal charges being filed.
****** From formal charges being filed to conclusion of disciplinary case.
******* From date investigation completed to date of final disposition of disciplinary case.

From 1994 through late 1999, the board had substantial and increasing difficulty in recruiting quality pharmacists for its 21.5 inspector and supervising inspector positions due to substantial salary inequities with the salaries paid to private-sector pharmacists. The board's inspectors are the cornerstones of the board's enforcement activities, and without sufficient quality inspectors, the board could not and cannot perform the essential consumer protection activities needed for a vigorous, swift and equitable enforcement program. As such, the board experienced substantial inspector vacancies during this period and pursued extraordinary efforts to increase the salaries of its inspectors to become better able to attract quality pharmacist applicants. In fact, at the time of the last sunset review, the board had requested the committee's assistance in obtaining higher inspector salaries. This support did come via introduction of legislation in two separate years to link the inspectors' salaries with that of University of California pharmacists. However, these provisions were opposed by the administrations of two governors, and amended out of the bills. Other efforts to obtain a special salary adjustment for inspectors included reclassification and designation as under-compensated workers (again, both processes were denied). Finally during 1999 collective bargaining sessions, the board was able to secure a special salary adjustment for its inspectors, which resulted in a 22 percent salary increase over an 18-month period. As a result, the board was able to recruit and hire high-quality applicants (all inspectors positions are now filled; 11 of the board's 20 inspectors have been hired since mid-1999).

Meanwhile the board implemented new procedures to redirect duties away from its inspectors that did not require the knowledge of a pharmacist. For example complaint processing, audit input, evidence photocopying and license review were either reassigned to other staff or budget change proposals were written to create staff to perform these functions. Not all the staff needed and requested were approved (see the budget change proposal table for a complete list), but the board was able to obtain permanently some of these staff positions. And until positions were approved through the budget process, the board administratively established limited-term positions to review site licenses and track and mediate complaints.

Simultaneously, the board directed all inspectors to work exclusively on investigating complaints. These actions were effective in reducing the backlog of growing complaints and decreasing complaint processing times. Additionally, all routine inspections were stopped in early 2000 when the backlog reached its zenith, at which point board supervisors focused all inspectors' efforts at completing the oldest cases. During Enforcement Team Meetings, the case status of all investigations and complaints were discussed both to target necessary deadlines for completion of work and identify progress in reducing the backlog.

By the end of 2000/01, the board had made substantial progress in resolving its backlog of complaints, and by 2001/02 generally was meeting its performance standards for investigations and mediations.

Since the last sunset review, the board has reduced the time it takes to investigate or mediate complaints. The board took 139 days at the time of the prior sunset report, and currently takes 83 days to investigate complaints – a reduction of 56 days or 40 percent faster *(see Table 24 on the previous page).*

The board also reduced the time required to mediate complaints. It previously took an average of 126 days to mediate complaints; currently the board takes 91 days. This is a reduction of 35 days (or 28 percent faster).

However, once the investigation report is complete, the board is taking longer to review and refer a case to the Attorney General's Office. Formerly it took 51 days; today it takes 181 days – more than 3 times as long. The greatest delay in this review process is for the board's supervising inspectors to review the cases and refer them to the executive officer recommending a referral to the Attorney General's Office (a review step which is required). The problem causing this substantial delay is that the board has an insufficient supervisor-to-staff ratio over its inspectors to allow the supervisors to do all elements of their jobs timely. The board has only two supervisors to supervise, manage and train the board's 20 inspectors all of whom work from home offices and do not report to a board office except quarterly. Moreover, the extensive travel requirements of the supervising inspector positions coupled with the additional administrative and other necessary duties required make it difficult to perform all priorities within a short timeframe. Whereas priority cases get expedited handling through the system, not all serious cases are so handled due to the press and volume of other assignments.

Action to reduce this delay is in the works: in 2002/03, the board will receive one new supervising inspector position and convert one inspector position to a supervising inspector position as a result of budget change proposals submitted in 2001/02. These augmentations will result in a supervisor-to-staff ratio of one supervisor to five inspectors – a reasonable span of control. As a result, case management, investigation feedback and case review will occur more routinely, and this unacceptable delay in reviewing cases will be substantially reduced. In the interim, the board is also specially routing serious investigations to the supervisors to facilitate case review.

Once the cases have been referred to the Attorney General's Office, it takes an average of 188 days for that office to prepare and file a pleading (accusation or statement of issues); this is 52 days longer than reported in the board's last sunset review (a delay of 38 percent longer). And after the pleading has been filed, it takes 395 days for the final resolution of the matter, whereas before it took 264 days at the time of the last sunset review. This process is now 131 days longer.

The board's strategic plan targets one year as the performance standard for case resolution once an investigation has been sent to the Attorney General's Office. Currently the board is experiencing a time frame of 583 days for this.

Overall, the number of days it takes to investigate and resolve a serious complaint that is sent for formal discipline is 847 days – this is about 2 1/3 years. This is about seven months longer than it took previously.

Complaint aging data for the last four years for phases of the investigation process are provided below for a sample of cases.

Table 25 – Investigation Case Aging

INVESTIGATIONS COMPLETED WITHIN:	FY 1998/99	FY 1999/00	FY 2000/01	FY 2001/02	Average % Cases Closed
90 Days	38	69	201	359	23.1%
180 Days	78	97	243	161	20.1%
1 Year	194	197	230	23	22.3%
2 Years	232	250	288	3	26.8%
3 Years	38	60	76	1	6.1%
Over 3 Years	12	24	10	1	1.6%

Table 26 – Mediation Case Aging

MEDIATIONS COMPLETED WITHIN:	FY 1998/99	FY 1999/00	FY 2000/01	FY 2001/02	Average % Cases Closed
90 Days	16	35	100	138	25.1%
180 Days	24	76	102	66	23.3%
1 Year	32	111	103	10	22.3%
2 Years	51	122	63	0	20.5%
3 Years	46	16	13	2	6.7%
Over 3 Years	5	5	14	0	2.1%

Table 27 – Application Investigations Case Aging

APPLICATIONS COMPLETED WITHIN:	FY 1998/99	FY 1999/00	FY 2000/01	FY 2001/02	Average % Cases Closed
90 Days	244	265	261	269	47.1%
180 Days	116	175	221	161	30.5%
1 Year	148	107	135	24	18.8%
2 Years	55	17	4	0	3.4%
3 Years	4	2	0	0	0.3%
Over 3 Years	0	0	0	0	—

Table 28 – Attorney General Case Aging

AG CASES COMPLETED WITHIN:	FY 1998/99	FY 1999/00	FY 2000/01	FY 2001/02	Average % Cases Closed
1 Year	13	18	18	42	28.3%
2 Years	28	31	36	37	41.0%
3 Years	11	8	18	19	17.4%
4 Years	5	5	4	4	5.6%
Over 4 Years	5	2	4	14	7.8%
Total Cases Completed	62	64	80	116	
Disciplinary Cases Pending	236	204	205	174	

The board's performance in 2001/02 was substantially better than its average performance over the four year period in closing complaint investigations (95 percent of the complaints were closed within 180 days in 2001/02 versus 43 percent during the four-year period); again reflecting the significant achievements of full inspector staffing and case management.

The case aging data for the cases referred to the Attorney General's Office for resolution is improved from that reported during the last sunset review. The board currently closes 68 percent of its Attorney General's Office-referred cases within two years; during the last sunset review this was 38 percent.

However, one of the board's strategic objectives is to reduce enforcement prosecution time to one year from the date a case is referred to the Attorney General's Office. The board has one analyst where a portion of her duties now are to manage pending caseload at the Attorney General's Office among the many attorneys who work on board cases. The board believes that by managing its cases referred to the Attorney General's Office, and working with each attorney assigned to board cases, there will be a reduction in case completion times. This has already had an impact -- the number of cases resolved in 2001/02 increased to 116 from 80 in 2000/01 (and an average of 63 for the two years before that).

Citation and Fine Program

Over the last seven years, the board's use of citations and fines as an enforcement option to ensure compliance with pharmacy law has greatly expanded. In July 1995, the board's first regulation to authorize the imposition of citations and fines was implemented for only two types of violations – failure to provide patient consultation and unlicensed activity.

In March 2000, the board added failure to fulfill continuing education requirements as a third violation type that could be subject to citation and fine penalties.

In July 2001, substantially broadened new board regulations took effect that authorize the board to cite and fine for any violation of pharmacy law.

The Legislature envisioned citations and fines as important disciplinary tools when it created the statutory authority of a regulatory board to develop implementing regulations to activate the use citations and fines. The board has found citations and fines to provide valuable intermediate sanctions between informal admonition and formal disciplinary action over the years, corresponding with the board's actions to broaden its regulations to increase the use of this option.

In implementing the recent changes to its citation and fine regulations in early 2002, the board's legal counsel advised that a new process would be needed from a decades old Compliance Committee structure. The Compliance Committees had served as a process for board members to discuss publicly violations of pharmacy law with both the responsible parties and pharmacy management, with the goal of bringing licensees into compliance with pharmacy law, but with the exception of failure to provide patient consultation, the Compliance Committees could not issue citations and fines for violations.

However, under the new regulations now all pharmacy and pharmacist violations are issued by a two-member Citation and Fine Committee of board members appointed by the board president. All other citations and fines (for non-pharmacy entities and individuals) may be issued by the executive officer. The new process allows an opportunity for any individual cited and fined to appeal. The appeals are ultimately decided by an administrative law judge. Citations and fines issued by the board are publicly disclosed.

The board began issuing citations and fines under the expanded authority in May 2002. Assessment of the board's use of citations and fines will occur through the Enforcement Committee's public meetings and by the board during its public meetings.

The data below show the amount of citations and fines collected over the prior four years.

Table 29 - Citations and Fines

CITATIONS AND FINES	FY 98/99	FY 99/00	FY 00/01	FY 01/02
Total Citations	112	32	90	207
Total Citations With Fines	112	32	90	207
Amount Assessed	$113,600	$54,500	$107,200	$87,796,750
Reduced, Withdrawn, Dismissed	20	10	11	11
Amount Collected	$76,312	$57,750	$109,300	$49,600

The extraordinary spike in the amount of fines assessed by the board in 2001/02 is due to the $88.7 million fine issued by the board in May 2002 to one California pharmacy and two pharmacists who were dispensing medications to patients via the Internet without valid prescriptions. These fines were authorized by SB 1828 (Speier, Chapter 68, Statutes of 2000), and are believed to be larger than any fine issued by a regulatory agency (and are currently under appeal by the cited parties). Nevertheless, the issuance of the fines reflects the board's value of citations and fines as important consumer protection tools to deter violations of law by licensees. In this case over 3,500 instances were cited of California patients receiving medication without valid prescriptions (that require a health-care provider's examination of a patient and knowledge about a patient's health or pre-existing conditions). Additionally, investigations of Internet firms are underway and more citations and fines may be issued under this authority in the future.

The board is also seeking to the citation and fine process in new enforcement actions in the future. In 2002, the board approved regulations to increase its authority to issue fines for up to $25,000 per violation for dispensing a prescription medication or device via the Internet without a valid prescription or good faith examination by a physician. The board simultaneously approved a regulation to cite and fine for violations of the Confidentiality of Medical Information Privacy Act. These regulations are currently under review by the Administration as part of the rulemaking process.

This year the board is seeking additional authority to cite and fine, this time for Internet violations via SB 1828 Speier (Chapter 68, Statutes of 2000). The board can fine up to $25,000 per violation for dispensing a prescription drug or prescription device over the Internet without a valid prescription or provide a prescription via the Internet without a good faith examination by a physician.

The board is also seeking regulation authority this year to cite and fine for violations of patient privacy provisions provided n the Confidentiality of Medical Information Act and for Internet violations (via specific authority in the board's regulations). These regulations have been adopted by the board but are undergoing review at the time this sunset review is being written.

Diversion Program

In 1985, the board sponsored legislation that required the board to develop a Pharmacist Recovery Program (PRP). This program identifies and rehabilitates chemically dependent or mentally impaired pharmacists or interns. The general process requires evaluating the nature and severity of the chemical dependency and/or mental illness, developing a treatment plan and contract, monitoring participation and providing encouragement and support for the successful completion of the program, typically in three to five years.

The program fulfills two distinct purposes -- the PRP serves as a diversion program to which the board may refer pharmacists and interns either in lieu of discipline or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists and interns who may enter the program on a voluntary basis and without the knowledge of the

board. Regardless of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Table 30 – Diversion Program

DIVERSION PROGRAM	FY 98/99	FY 99/00	FY 00/01	FY 01/02	Total
Total Program Contract Costs	$65,648	$76,684	$63,268	$81,155	$249,494
Total Participants	54	57	56	63	232
Successful Completions	7	8	9	10	34
Unsuccessful Completions	4	4	6	5	19
Not Eligible/Not Appropriate	2	2	4	1	7

Board policy is to speed the entry into the PRP rather than wait until the completion of an investigation by informally referring pharmacists during the course of an investigation. However, the pharmacist or intern must voluntarily contact the program and undergo an intake evaluation and assessment. This early intervention assists the licensee in beginning his or her recovery, and results in the pharmacist or intern receiving treatment and being monitored while the case is being investigated.

The Board of Pharmacy uses a Pharmacy Review Committee (PRC) to review and determine the proper treatment for all board-referred participants. The PRC is comprised of the assigned clinical case manager from the contracted employee assistance program provider, as well as one board inspector and one board analyst who are both trained in drug recognition and the treatment of substance abuse. The PRC meets monthly to discuss participants' treatment contracts, compliance and assessment notes as well as to review any participant requests.

Each participant's treatment contract and compliance are reviewed on a quarterly basis by the PRC. However, participants' treatment contracts may be reviewed more frequently if needed based upon a participant's request or because of compliance issues.

The treatment contracts of all self-referred participants and board informally referred participants are monitored solely by the clinical case manager -- thereby ensuring the confidentiality of these participants as required by statute. In the event that a self-referred or board informal participant is deemed to be a threat to him or herself or to the public, the contractor is required by law to notify the board. This notification ensures that the board's public protection mandate is met.

Most treatment plans are from three to five years in length. Participants are required to pay for the costs of their own treatment as well as the costs of biological drug testing, which is ordered randomly and sometimes collected in the field by monitors. This subsidizes a portion of the administration costs associated with the program (shown in the table above).

A typical treatment contract for a substance abuse or a dual diagnosis (substance abuse with a mental health diagnosis) participant includes: mandatory attendance at AA meetings (12-30 meetings per month), attendance at health-support group meetings (one to two per week), biological drug testing (18-36 times annually), submission of monthly self reports, and

sometimes participation in individual therapy or other types of support groups. Periodic assessments by independent clinicians also are completed on participants at the direction of the board. Additionally, participants working in the field of pharmacy must have a work-site monitor in place whose function is to monitor the functioning of the participant on a continual basis, provide monthly reports to the program and notify the program immediately of any suspected use or irregularity.

Specially trained board inspectors also make periodic visits to PRP participants' worksites and meet to discuss pharmacy practice issues as well as sobriety. The board uses this information to validate information provided by the contractor as well as to evaluate the contractor's performance.

Participants who are terminated from the program for failure to derive benefit or noncompliance are immediately referred to the board's Enforcement Unit for investigation and referral to the Attorney General's Office for expedited formal discipline due to the imminent danger to the public of such individuals continuing to practice.

Of the 65 participants in the program in June 2002, 17 are self-referrals, and 25 are on formal probation with the board.

The PRP ensures that licensees afflicted with mental illness or chemical dependency receive the treatment and the rehabilitation (and monitoring) they need to return to normal and productive work.

Results of Complainant Satisfaction Survey

In October 2000, the board implemented a customer satisfaction survey, fulfilling one of the board's strategic activities. The survey requests consumers' assessments of the board's complaint resolution activities.

A postcard survey form of four questions is mailed with the complaint closure letter to consumer complainants once the board completes its work on a case. Each question requests a rating from 1 to 5, with 5 being the highest level of satisfaction. There is also an area in which written comments can be added.

Currently 65 percent of those filing complaints with the board and responding to the board's survey cards are satisfied with the board's handling of the complaint. And 72 percent are satisfied with the board's assistance to them. Of those who are dissatisfied, consumers are most unhappy with the time taken to complete the investigation, the information provided regarding the complaint's status or status of the investigation is not sufficient, or the disciplinary sanctions imposed by the board should be higher.

The board is working to improve the satisfaction level of its complainants. Over the past several years, the board has requested additional complaint mediation staff to reduce closure times as well as to provide status information to those whose complaints are not yet resolved.

Most of the respondents' complaints regarding the board were investigated or mediated before the board's closure times dropped to 90 days or less. Additionally the board has revised its closure letter to increase the amount of information provided to the consumer and will revise the consumer brochure to provide a fuller explanation of the investigation and mediation processes and outcomes.

Typically, those who respond to such mail surveys are those with strong feelings about the process, typically strong negative feelings about the process. To obtain data from consumers through another means, in 2002/03 the board will use telephone surveys of complainants to seek feedback on consumer satisfaction. This way the board can reach a wider cross-section of complainants, not just those who were motivated enough to complete a short survey.

Table 31- Complainant Satisfaction Survey Results

COMPLAINANT SATISFACTION SURVEY RESULTS*				
Questions	**Percent Satisfied by Calendar Year**			
	1999 *	**2000**	**2001**	**2002**
# Surveys Mailed:	*	nda	nda	nda
# Surveys Returned:		13	299	73
1. Were you satisfied with the way your complaint was handled?	*	46%	65%	65%
2. Were your questions or concerns regarding your complaint or the complaint process answered to your satisfaction?	*	54%	66%	63%
3. Were you satisfied with the outcome of your complaint?	*	36%	62%	63%
4. Were you satisfied with the staff's assistance to you?	*	55%	73%	72%

* The Board began sending customer satisfaction surveys to consumers in October 2000.
nda – No data available in calendar year format.

ENFORCEMENT EXPENDITURES AND COST RECOVERY

Average Costs for Disciplinary Cases

Table 32 below displays the board's costs for investigating and disciplining licensees over the last four years.

Table 32 - Average Cost Per Disciplinary Case

AVERAGE COST PER CASE INVESTIGATED	FY 98/99	FY 99/00	FY 00/01	FY 01/02	OVERALL AVERAGE PER FY
Cost of Investigations	$173,068	$192,392	$223,217	$301,835	
Number of Cases	71	67	87	112	
Average Cost Per Case	$2,438	$2,872	$2,566	$2,695	**$2,643**
AVERAGE COST PER CASE REFERRED TO AG	**FY 98/99**	**FY 99/00**	**FY 00/01**	**FY 01/02**	**OVERALL AVERAGE PER FY**
Cost of Prosecution, Hearings, & Experts	$587,231	$548,892	$521,351	$1,218,764	
Number of Cases	71	67	87	87	
Average Cost Per Case	$8,270	$8,192	$5,992	$10,882	**$8,334**
Average Cost Per Disciplinary Case	**$10,708**	**$11,064**	**$8,558**	**$13,777**	**$11,027**

The top portion of this table displays the board's costs to investigate the cases each year that were ultimately resolved via formal discipline. The second portion of the table displays the costs charged by the Attorney General's Office, Office of Administrative Hearings and expert witnesses to finalize these same cases each year.

The costs to the board for investigating cases over the four-year period are relatively constant, with an overall average of $2,643 per case (based on yearly averages) across all four years.

However, the costs for administrative discipline for each year swing widely, reflecting the unpredictable nature and associated costs of the formal disciplinary process. A small number of expensive enforcement cases resolved in 1999/00 and 2001/02 are responsible for the high disciplinary costs these years that increased the average costs per case.

Of the 337 cases reported in Table 32 (above) that were completed, the average cost per case over the entire period (regardless of the year completed) was:

- $2,642 for the board's investigation costs
- $8,534 for the board's disciplinary costs for the Attorney General, Office of Administrative Hearings and evidence/expert witnesses
- $11,177 total cost per case

The average cost in 2001/02 of investigating a case where violations were substantiated, but the violations were not sufficient to warrant referral for formal discipline (where a citation and fine was issued, the matter was referred to the now disbanded Compliance Committee, or the case closed with a violation notice issued) was $1,550.

To calculate these average costs of formally prosecuting different types of cases, the board picked four categories of cases for each of the four years:

1. Unprofessional Conduct
2. Diversion of Drugs
3. Criminal Convictions
4. Statement of Issues

Table 33 - Average Cost Per Unprofessional Conduct Disciplinary Case (Actual)

Average Cost Per Unprofessional Conduct Case Investigated	FY 98/99	FY 99/00	FY 00/01	FY 01/02	Overall Average Per Case *
Cost of Investigations	$30,006	$109,623	$47,263	$98,344	
Number of Cases	14	10	15	30	
Average Cost Per Case	$2,143	$10,962	$3,151	$3,278	**$4,134**
Average Cost Per Unprofessional Conduct Case Referred to AG	**FY 98/99**	**FY 99/00**	**FY 00/01**	**FY 01/02**	**Overall Average Per Case ***
Cost of Prosecution, Hearings & Experts	$104,918	$213,485	$93,830	$255,943	
Number of Cases	14	10	15	30	
Average Cost Per Case	$7,494	$21,349	$6,255	$8,531	**$9,684**
Average Cost Per Disciplinary Case	**$9,637**	**$32,311**	**$9,406**	**$11,809**	**$13,818**

* Average cost per case regardless of year completed.

Table 34 - Average Cost Per Drug Diversion Disciplinary Case (Actual)

Average Cost Per Diversion Case Investigated	FY 98/99	FY 99/00	FY 00/01	FY 01/02	Overall Average Per Case *
Cost of Investigations	$61,416	$25,834	$120,012	$231,700	
Number of Cases	21	12	28	41	
Average Cost Per Case	$2,925	$2,152	$4,286	$5,651	**$4,303**
Average Cost Per Diversion Case Referred to AG	**FY 98/99**	**FY 99/00**	**FY 00/01**	**FY 01/02**	**Overall Average Per Case ***
Cost of Prosecution, Hearings, & Experts	$202,699	$61,795	$211,688	$183,633	
Number of Cases	21	12	28	41	
Average Cost Per Case	$9,652	$5,149	$7,560	$4,479	**$6,469**
Average Cost Per Disciplinary Case	**$12,577**	**$7,301**	**$11,846**	**$10,130**	**$10,773**

* Average cost per case regardless of year completed.

Table 35 - Average Cost Per Criminal Conviction Disciplinary Case (Sample)

Average Cost Per Criminal Conviction Case Investigated	FY 98/99	FY 99/00	FY 00/01	FY 01/02	Overall Average Per FY
Cost of Investigations	$5,712	$12,378	$3,356	$4,648	
Number of Sample Cases Compiled	8	8	8	8	
Average Cost Per Case	$714	$1,547	$420	$581	**$816**
Average Cost Per Criminal Conviction Case Referred to AG	**FY 98/99**	**FY 99/00**	**FY 00/01**	**FY 01/02**	**Overall Average Per FY**
Cost of Prosecution, Hearings, & Experts	$64,366	$27,519	$24,409	$28,270	
Number of Sample Cases Compiled	8	8	8	8	
Average Cost Per Case	$8,046	$3,440	$3,051	$3,534	**$4,517**
Average Cost Per Disciplinary Case	**$8,760**	**$4,987**	**$3,471**	**$4,115**	**$5,333**

Table 36 - Average Cost Per Statement of Issues Disciplinary Case (Sample)

AVERAGE COST PER STATEMENT of ISSUES CASE INVESTIGATED	FY 98/99	FY 99/00	FY 00/01	FY 01/02	Overall Average Per FY
Cost of Investigations	$9,332	$1,536	$1,536	$1,536	
Number of Sample Cases Compiled	8	8	8	8	
Average Cost Per Case	$1,166	$192	$192	$192	**$436**
AVERAGE COST PER STATEMENT of ISSUES CASE REFERRED TO AG	**FY 98/99**	**FY 99/00**	**FY 00/01**	**FY 01/02**	**Overall Average Per FY**
Cost of Prosecution, Hearings, & Experts	$29,505	$31,687	$33,127	$35,494	
Number of Sample Cases Compiled	8	8	8	8	
Average Cost Per Case	$3,688	$3,961	$4,141	$4,437	**$4,057**
Average Cost Per Disciplinary Case	**$4,855**	**$4,153**	**$4,333**	**$4,629**	**$4,493**

The board's average costs are greatest to discipline unprofessional conduct cases ($13,818 per case over the four years), followed by drug diversion ($10,773 per case), and based upon a sample of 32 cases criminal conviction cases ($5,333), and statement of issues ($4,493).

Unprofessional conduct cases that are sent for formal discipline involve a broad spectrum of serious violations of pharmacy law and sometimes multiple instances of the same or a diversity violations, including gross negligence, probation violations, allowing unlicensed activity, serious security violations, out-of-state discipline, dispensing medication without prescriptions and filling erroneous prescriptions. These cases are expensive to prosecute and may require additional expert witnesses.

Drug diversion cases are typically complex cases for the board to investigate and prosecute. They require detailed drug audits of drugs acquired, dispensed, and unaccounted for – a very laborious and time-consuming process for the board's inspectors. And they remain complex following referral to the Attorney General's Office and during administrative hearings. Sometimes these cases require additional expert witnesses (besides the board's inspectors).

The board's costs for pursing discipline of criminal convictions cases are $5,333. In these cases, the board becomes aware of a criminal conviction via a written or telephone report. The board typically then obtains the court documents and then writes a summary report; in many cases, this will be done by an enforcement analyst. The written investigation report is then sent to the Attorney General's Office for administrative action; consequently the prosecution costs are also lower for these cases than for the prior two categories of cases.

The board's costs for statement of issues cases (which are used to deny an application) lower cost enforcement cases as well. Enforcement analysts may also prepare these investigation reports which when forwarded to the Attorney General's Office, result in the lowest prosecution costs of the four categories of cases examined.

Obtaining Prosecution Costs

The board has experienced significant difficulty in obtaining the necessary funding to pursue cases at the Attorney General's Office in the last four years, and the lack of funding has impacted the board's enforcement program by causing the withholding of cases or delaying action on these serious cases because of the deficiency. The board has sought four separate budget change proposals or deficiency augmentations since December 1999 to maintain its access to legal services from the Attorney General's Office. Most of these requests were denied or when approved, substantially reduced by the Department of Finance. This was extraordinarily frustrating to the board as during the same period, the board had a growing reserve in its fund that ultimately reached 24 months (and despite a fee reduction in July 1999 that reduced most board fees to their statutory minimums). This funding inadequacy still plagues the board: in July 2002, the board is seeking augmentation of its Attorney General's budget of $300,000 for 2002/03 and ongoing years to prevent cutbacks in the level of Attorney General services needed by the board for its enforcement program.

- In 1998/99, the board overspent its Attorney General budget by $120,000. The board had a number of vacant inspector positions during the same year and was able to redirect money from salary savings to prevent a reduction in Attorney General services. This was also the first time that the board had overspent its Attorney General budget.

- In 1999/00, the board again continued to overspend its Attorney General budget. Moreover, because the board was finally successful in obtaining a substantially higher salary for inspectors during the July 1999 collective bargaining sessions (which indicated that the board would be able to fill its vacant inspector positions very soon) the board sought a $325,000 deficiency augmentation in early 2000. This augmentation was denied by the Department of Finance. The board ultimately overspent its Attorney General budget in 1999/00 by $325,000, which was covered by reductions in other program areas.

- In August 2000, the board submitted another Attorney General augmentation request for current year augmentation of $383,000, 2001/02 augmentation of $541,000 and ongoing augmentation of $371,000 annually. The Department of Finance denied the $383,000 current year augmentation, approved the $541,000 augmentation and decreased ongoing augmentation to $135,000 annually.

  The result was a deficiency augmentation request submitted in February 2001 of $431,000, which was partially funded by the Department of Finance at $143,000. Concurrently, because the board had filled nearly all its inspector positions, the board had to withhold cases referred to the Attorney General's Office until 2001/02, reduce Attorney General hours in May and June 2001, cancel purchases of new computer equipment and delay printing one *Health Notes* until 2001/02.

- During budget construction for the 2002/03 budget year, the board sought augmentation of $260,000 for Attorney General services via another budget change proposal. This was denied.

The board's Attorney General budget for 2002/03 is $777,475, which includes an adjustment of $80,576 for increased Attorney General rates and $6,670 for the new sterile compounding licensure program. Removing this adjustment leaves an Attorney General budget of $690,229.

Actual Attorney General expenditures over the prior years have been:

1998/99	1999/00	2000/01	2001/02
$642,178	$832,708	$860,036	$963,651*

*Actual expenditures were $1,076,651 but this includes an $113,000 augment for increased Attorney General rates; for ease of comparison across years, this amount has been removed

For this reason, the board is seeking an augmentation again for 2002/03 and ongoing years to maintain its access to Attorney General services.

Cost Recovery Efforts

The board relies upon the general cost recovery provisions of Business and Professions Code section 125.3 to seek recovery of enforcement expenses for formal discipline.

The board's policy is to seek cost recovery in all cases where cost recovery is authorized. (For example the board cannot seek cost recovery for statement of issues case.) Reimbursement of board costs is a standard term of probation listed in the board's *Disciplinary Guidelines*. The board seeks the award of costs when settling cases with a stipulation as well as with decisions provided through an administrative law hearing. However, the board cannot obtain cost for statement of issues cases and only rarely when revocation of a license occurs.

Table 37- Cost Recovery

COST RECOVERY DATA	FY 98/99	FY 99/00	FY 00/01	FY 01/02
Total Administrative Enforcement Expenditures **	$760,299	$741,284	$744,568	$1,520,599
# Potential Cases for Recovery *	52	47	63	71
# Cases Recovery Ordered	48	42	57	67
Amount of Cost Recovery Ordered	$299,293	$289,262	$345,842	$392,690
Amount Collected	$170,664	$155,880	$238,992	$250,880

* The "Potential Cases for Recovery" are those cases in which disciplinary action has been taken based on a violation, or violations, of the pharmacy law. Does not include statement of issues cases on applications.

** Does not include board investigation expenses, only those incurred by the Attorney General's Office, Office of Administrative Hearings, and evidence.

Over the last four years, the board has been awarded $1,327,087 in costs, and has collected $816,416. The amount awarded and collected has been steadily increasing over the four years displayed in the cost recovery table above. Typically most costs awarded to the board are paid in installments, over a period of time; so money awarded as costs in one year may not be fully collected until the end of the probation period, perhaps in five years.

Restitution Provided to Consumers

The board occasionally includes restitution as an optional term of probation for pharmacists, pharmacist interns and facilities. When an accusation against a licensee is filed, the board's *Disciplinary Guidelines* provide the framework for determining the discipline or settlement in

that case. Restitution may be ordered if such a remedy is appropriate. However, most cases referred for formal discipline (typically drug diversion, controlled substance abuse, security lapses) do not result in a restitution order, and accordingly, the board rarely applies restitution as a condition of probation.

The board added, "Evaluating the feasibility of ordering restitution for prescription error cases in which the patient suffered minor economic harm," to its strategic plan in April 2002. Historically, it is rare for the board to submit prescription error cases for formal discipline and there is little the board can do to make consumers whole for the costs that can attend a prescription error (lost work time, doctor's office visit, etc.) During a public meeting of the Enforcement Committee and during the July 2002 board meeting, the board decided against proceeding with this activity. Concluding that the award of restitution is within the purview of the civil courts system, the board decided that it could not interject itself in this matter as it lacks the resources and knowledge to award damages. However, the board's long-standing expectation is that should a prescription error occur, the board expects the pharmacy to initiate activities to assure the patient receives the correct, prescribed medication and encourages a refund of any fees paid for the incorrect medication.

Complaint Disclosure Policy

The board discloses and provides specific complaint and disciplinary information and certain documents in accordance with the Public Information Act, Section 6250, et. seq. of the Government Code.

Table 38 - Public Disclosure of Licensee Information

Type Of Information Disclosed	Yes	No
Complaint Filed	✓	
Citation	✓	
Fine	✓	
Letter of Reprimand	✓	
Pending Investigation		✓
Investigation Completed	✓	
Arbitration Decision	✓	
Referred to AG: Pre-Accusation		✓
Referred to AG: Post-Accusation	✓	
Settlement Decision/Proposed Decision	✓	
Disciplinary Action Taken	✓	
Civil Judgment *	✓	
Malpractice Decision *	✓	
Criminal Violation:		
Felony	✓	
Misdemeanor	✓	

The board will disclose that the source of the complaint investigation is a civil judgment or malpractice decision and whether a pharmacy law violation was substantiated but does not disclose details or disposition that was not initiated by the board.

Upon written request, the board provides a written summary of the disposition of any substantiated complaint against a licensee received within the last five years, and any formal disciplinary action within the last 10 years. For substantiated complaints, the board provides the requesting party with the date the complaint was received, the name and title of licensees involved, a summary of the complaint and the disposition of the complaint including any non-disciplinary action taken (e.g. correction ordered by the board, notice of violation issued, citation issued – with or without a fine), or whether the case was referred to the Attorney General's Office for formal disciplinary action. For disciplinary cases, copies of any public documents are released, which includes a copy of the accusation filed alleging violations of pharmacy law and the final disciplinary decision.

The board will also provide a written summary of any routine compliance inspections completed within the last five years. This includes a summary of any corrections ordered.

All formal disciplinary actions are published in the Board of Pharmacy's newsletter, which is distributed to licensees, professional associations, and other interested parties. The information disclosed includes a licensee's name, license number, city, effective date of action, penalty and the violations involved.

If the requested records and information falls within the board's record retention period and are still available for release, the board does not have any problems with obtaining information. The board routinely requests staff counsel review of record requests to ensure the board's legal authority to release the information.

CONSUMER OUTREACH, EDUCATION AND USE OF THE INTERNET

The board has a public outreach program to advise consumers about the board and its consumer protection purpose, educate consumers about how to take their prescription medication appropriately, the health benefits or risks for compliance (or noncompliance) with drug regimens, and what questions consumers should understand before they take prescription or over-the-counter medications. The board has a diversity of consumer education materials, some in multiple languages. There is also a component to upgrade the knowledge of board licensees, and keep them advised about pharmacy law and board policies.

The importance and structure of the board's public outreach program is described in the Board Committees section of this report under the Communication and Public Education Committee. An excerpt of this description is repeated on the next two pages as an overview of consumer outreach and education.

The California Board of Pharmacy has twice won national awards for its public education program. In 1999, the board won the *Paul G. Rogers Award* from the National Council for Patient Information and Education for outstanding leadership in the development, production, and dissemination of educational public services. The board's program was noted for its focus to enhance consumers' understanding of the value of high quality communication about medication, and the development and advancement of public policy to support improved medication communication.

In 1997, the board won the *Fred T. Mahaffey Board of the Year Award* from the National Association of Boards of Pharmacy for the state pharmacy board demonstrating outstanding leadership in protecting the public.

The board's communications and outreach program is divided into components:

- *Health Notes*, which is a compendium of up-to-date treatment methodologies and issues on a specific health care topic, published in a monograph format for pharmacists and useful to other health care providers as well as to the public,
- brochures and newspaper columns to educate consumers about how to take their medications, the role of the board, how to file a complaint and health columns based on excerpts from *Health Notes* and other consumer brochures and health care issues,
- public forums, where the board works with local activists to arrange health fairs, staffed by pharmacists to respond to patients' inquiries and covered by local media to disseminate the board's message to a wide audience,
- online availability of board publications to the public at the board's website (www.pharmacy.ca.gov).

The board has other public information functions, specifically:

- Producing four newsletters annually for licensees, advising them of new laws and regulations, board policies, compliance issues, and disciplinary actions taken by the board.

- Responding to press inquiries, which are becoming an ever-growing source of workload. Primary areas of inquiry in recent years have been the purchase of drugs over the Internet, patient privacy of prescription records, the number of prescription errors made by pharmacists, and the three deaths in 2001 due to a pharmacy's negligence in compounding medications.

Six years ago the board implemented its public outreach program through a series of four budget change proposals (budget change proposals). Four budget change proposals were required because only a portion of the program was approved in any year, and then on a limited term basis, and generally without any staff to perform the duties. Finally in July 2001, the board received one staff position in the budget; however the October 2001 hiring freeze blocked the board's ability to fill the position (an individual had been interviewed but had not yet been offered the position), and the position will likely be lost due to cost cutting to reduce the state's deficit.

The board's public outreach is substantially impacted by the lack of this staff position, specifically in terms of the public outreach events the board coordinates and/or attends, and the board's ability to develop new consumer materials that respond to emergent issues.

The only way the board can provide optimal consumer protection is to assure patients know the importance of following drug therapy and how to advocate for their own interests and health in dealing with prescription drugs.

Public education is an essential element in the board's ability to provide for the public protection. To do this the public needs to know that the Board of Pharmacy exists, that it is a consumer protection agency that will assist them with jurisdictional complaints, and most importantly needs to be contacted about the questionable behavior or practices of any board licensee.

Moreover, the board's public outreach program serves a second important function to educate consumers about how to take their prescription medications, and how to minimize their risks of medication errors.

The board wholeheartedly agrees with a conclusion of the Little Hoover Commission in 1998 supporting the need for consumer education: "To be sure, government cannot pretend or aspire to protect all consumers in every transaction. That reality is among the reasons why consumer education is the best protection," *Little Hoover Commission 1998*. The need for ongoing public education is essential for consumer protection in any area, but it is perhaps most necessary in the health care field where consumer protection has life saving benefits.

Online Information Available to Consumers

The board has a website from which it conducts business with the public and licensees. The address is www.pharmacy.ca.gov. There is information for consumers, licensees, applicants, and the public at large. The board believes it is highly feasible and appropriate to do business and outreach through the Internet, and the board received over 1.5 million hits on its website in 2001/02.

For consumers and the public generally, the board has a diversity of information including an online complaint form and information on how to file a complaint; consumer tips/patient information; submitting comments, complaints or suggestions about the board or the department; and information about patient consultation and a patient's bill of rights. All board public education brochures are available online.

The website provides license records and permits license verification, posts board minutes, agendas, actions of the board from the last meeting, board committee activities, and the strategic plan and quarterly program updates. The website also contains all regulations pending and recently enacted. All board newsletters and *Health Notes* are also available from the board's website, as are board legislative analyses on pending legislation.

For licensees and applicants, the board has its application forms and instructions online and background information about each licensing program, in addition to the items listed above. The board also includes the prices of the 50 top Medi-Cal drugs, so pharmacies can obtain this information readily. Board newsletters that contain important information about pharmacy law and interpretations of board law, and pharmacy law itself are available via the website.

Doing Business Online

The board strongly believes in the feasibility of doing business online with licensees and the public, and envisions there should be much progress in this realm in the future.

In early 2002, the board eliminated its "contact us" feature (that allows individuals to email the board directly with questions) from the website because of staff vacancies and the state's hiring freeze. The board saw this as an undesired and unwelcome change, yet one that was unavoidable without staff to respond to inquiries. The interactive feature on the board's website was a popular feature.

Nevertheless, the board does conduct a great deal of communication with licensees and others via e-mail, and board employees have e-mail addresses on their business cards to promote this method of communication. Application forms can be downloaded from the website and mailed to the board. Application forms to submit address changes can also be downloaded and mailed or faxed to the board for processing.

In the future the board envisions and desires the ability to allow licensees to renew their permits online and complete and submit applications electronically as well. Currently the board cannot accept credit cards for payment of renewal fees and is awaiting the completion of the department's testing of this technology. Additionally the technology permitting electronic signatures on applications is not yet available to the board and is the impediment to using this method of submitting applications (because the signatures of applicants are

important in the process), but given the rapid advances of technology and legislation authorizing the use of e-technology, this service may be available in the future.

Feasibility of Online Testing

The board has only one examination, which is for the licensure of pharmacists. The board develops this examination and administers it two times each year in large, convention center type facilities. Typically, 600 or more individuals take the examination in January and 1,200 take it in June. California is the only state to develop and use its own examination for the licensure of pharmacists; all other states use the National Association of Boards of Pharmacy examination (called the NAPLEX).

Since July 2001, the board has endorsed the use of the NAPLEX in California as the primary examination for assessing the minimum competency of pharmacists. In addition, the board approved the use of and passing of a separate California jurisprudence exam for any pharmacist wishing to be licensed in this state. The NAPLEX is a computer adaptive exam, and is widely available to applicants since it is administered throughout the U.S. on most weekdays (except holidays). The jurisprudence exam, which would be developed by California, would be accessible via the same computer administration structure, and when desired, at the same time as the NAPLEX.

However, the use of the NAPLEX requires the enactment of legislation and is controversial within the profession. The board itself did not have a unanimous vote of support from all members to authorize the transition to NAPLEX although, the majority of members did support this change.

The board believes it is both feasible and appropriate to administer the pharmacist licensure examination in an online testing mode, either using the NAPLEX or after conversion of the board's current California pharmacist license examination to a computer-based format over the next few years.

Expanding Internet Services

Expanded use of the Internet to provide board services would result in greater satisfaction and improved service to board licensees and the public, principally by reducing the time needed for payments, inquiries and applications to reach the board, and the time required to mail letters, responses or licenses out. Actual administrative streamlining would not occur to a substantial extent as the board's workload and duties to process applications, answer inquiries or confirm information would remain the same. The major exception would for the examination, which if converted to the NAPLEX would allow the board to redirect staff who currently work with scheduling candidates for the exam and arranging for details of administering the exam (convention center arrangements, hiring of proctors, exam site administration).

For example, online renewal would allow licensees to renew their licenses at their convenience and as well as allow them to renew their licenses within a much shorter timeframe than is possible by mailing in a check to a centralized cashiering office in the department. This can make a huge difference to licensees who renew their licenses near the end of their renewal periods (which they are legally allowed to do) — until the department

cashiers their check (thousands arrive daily) and updates the computer record, the licensee's record shows delinquent. As such, because they are health care practitioners, they cannot work unless they have active licenses. It may take seven to ten days before the department receives, cashiers, and updates the computer record. Online renewal would eliminate this.

Other Uses for the Internet

The board currently has a highly developed and user-friendly website. With the addition of Internet renewal, online submission of applications, and restoration of the interactive feature of consumer inquiry (which will resume after the hiring freeze ends and staff to provide this service are hired), the board will achieve a higher level of service with the public and licensees.

One area where the board may find it feasible in the future to expand its Internet services is to develop specialized online continuing education training modules that pharmacists can take to earn specific continuing education in areas important to the board.

The board may one day as well offer live feeds of board meetings on the Internet, a service that could greatly expand participation in these public meetings.

Emerging Trends Falling Under the Board's Authority

Pharmacies are beginning to compound drugs for physicians, hospitals, and patients when the drugs are unavailable from manufacturers. There are no standards for such compounding.

Groups of physicians, sometimes large groups of physicians, are operating pharmacies without the requirements for controls and staffing -- and hence safeguards for patients — that are required of pharmacies.

Prescription drugs are obtained from the Internet, without benefit of a valid prescription (which requires a prescription written by a prescriber who has performed a good-faith exam of the patient). Whereas these drugs are often lifestyle drugs (sexual performance, weight loss, hair restoration, etc.), there is increasing concern patients are obtaining drugs to treat other health conditions, such as antibiotics for sexually transmitted diseases. Such prescription drugs purchases can undermine the checks and balances of the prescription drug delivery system as well as public health mandates established to stop the spread of these diseases. Moreover, patients may not get the drug they believe they are obtaining via the Internet because of unscrupulous operations.

Drug samples that are not allowed in pharmacies continue to be found in pharmacies; however, pharmacies have proven to be the appropriate health care provider to oversee the distribution of drug samples to patients.

Future Challenges

The board's need to license and regulate to assure consumer protection requires constant evaluation of technology and the practices emerging in health care. Health care payers are looking for ways to reduce health care costs. Patients are seeking the convenience of "practice

without presence" health care as well as lower health care costs – and ultimately regulators will need to adjust for practice without presence, once it becomes legal.

The public's use of the Internet to purchase prescription drugs is one area pointing to consumer acceptance of this form of commerce in the future.

The high cost of prescription drugs is causing patients to purchase drugs from Mexico, Canada or elsewhere where the costs are lower. For example in Canada, prescription drug prices are about 30 to 50 percent lower than in the United States. Senior citizens, who take more prescription medications than the rest of the population, and who may be on maintenance medications for the rest of their lives, are the major parties seeking to reduce the amount they must pay for medications. Specialty firms have developed to assist patients in obtaining medication from outside the country, either via mail or by coordinating trips. While it is technically a violation of U.S. law to do this, the U.S. Customs Agency has "looked the other way" at those who bring back a 90-day supply of medication for personal use. However, the purchase of prescription medication from such sources, where the pharmacy providing the medication may change every few months, may cause a number of problems for patients – for example, no one pharmacist may be evaluating a patient's total drug therapy. For those patients who receive prescriptions from a number of health care providers – the result is contraindications that can be life threatening. The board, as well as all health care practitioners, needs to educate patients about such practices that may be dangerous to their health.

California law now allows pharmacists to practice pharmacy outside a pharmacy's premises, and pharmacists may practice drug management of patients without being directly linked to the dispensing of any drug product – instead "dispensing" information. Dispensing information can readily occur via the Internet as well as via telephone. Regulation of such professional services will be a change for the board.

The pharmacist shortage will continue to impact Californians, as well as the nation. Already California has 59 pharmacists per 100,000 people, well below the national average of 71 pharmacists per 100,000 people. This shortage of pharmacists will impact the dispensing of prescription medications to patients in a number of ways important to the board. For example, a shortage of pharmacists can result in too high a workload for on-duty pharmacists, which causes concern that prescription errors may increase by overworked and stressed pharmacists. Also, pharmacy hours are reduced if there are no available pharmacists to work, impacting the ability of patients to obtain necessary prescription medication. Moreover, the projected spike in prescription volume over a five year period without a comparable increase in the number of pharmacists, will require increasing use of technology and redefined duties of pharmacists to assure patients continue to receive pharmacists' care.

Simultaneously with the pharmacist shortage, increasing prescription volume, an aging population, and introduction of new prescription drugs and treatment modalities, the population of California will continue to develop into a more linguistically and culturally diverse populace, further increasing changes needed in the dispensing of prescription drugs by the pharmacy profession

The pharmacist shortage may also encourage the growth of "practice without presence." Last year, the board sponsored legislation to allow clinics to install automated medication dispensing machines with a video terminal that could be remote-controlled by a pharmacist who could release the medication to the patient after patient consultation face-to-face via video screens (AB 809, Salinas, Chapter 262, Statutes of 2001). Such dispensing machines allow the pharmacist to consult directly with patients at another location, extending the availability of pharmacists to a wider area simultaneously.

There is a tremendous financial (marketing) incentive for drug manufacturers to identify patients who take specific drugs. Such patients are especially attractive to manufacturers seeking to target specific types of drugs. But patient privacy is an issue. For example, in Florida recently patients were sent in the mail by a pharmacy – unsolicited (as well as unprescribed) — a new form of Prozac that needs to be taken only once a week instead of daily. At least one patient has sued the pharmacy for violation of patient privacy. As another example, in the last two years, one drug manufacturer conditioned the availability of medication for AIDS patients to those who provided their names to the manufacturer ostensibly because various laboratory tests are needed for monitoring patient health; however, the potential for privacy issue violations is tremendous here.

Drug manufacturers use targeted marketing either to encourage doctors to switch the medications patients are prescribed to their preferred brands or to encourage pharmacies to seek authorization from the prescribers to switch patients to a preferred drug.

Drug manufacturers now use a sizeable proportion of their advertising budgets on "direct to patient" advertising. Whereas years ago, drug manufacturers concentrated on prescribers to improve market share, today the advertisements to patients are a way of getting patients to demand from their prescribers, specific, brand-name medication for new products, where no generics exist and for drugs that are typically more expensive.

Alternative medications such as herbal remedies and dietary supplements are gaining widespread use by the public. But they have the potential for health endangering interactions with prescription and non-prescription medications. The interactions are not well known to the public and to many practitioners, and the products themselves frequently differ in strength from brand to brand. Approximately 20 percent of prescription drug users also take dietary supplements.

The high cost of prescription drugs is perhaps the most substantial factor influencing the public and its use of prescription medication. Whereas the board does not regulate prescription drug prices, the overall impact of the price of prescription medication and efforts by the public and third party payers to reduce these expenses greatly impacts consumer behavior as well as how the board regulates the profession.

Regulation of Internet Pharmacies

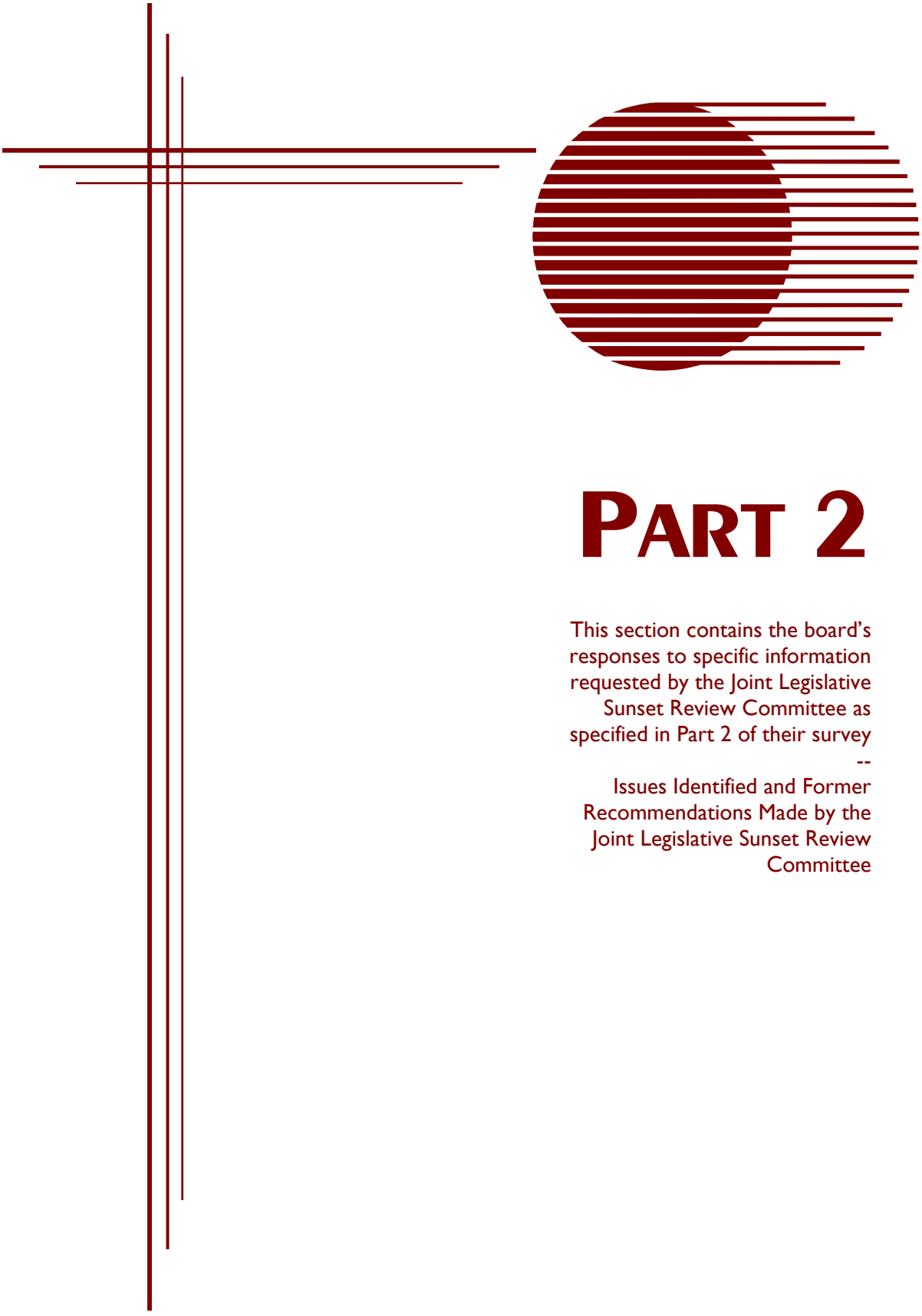
Pharmacies doing business over the Internet must be licensed by the board. If the pharmacy is located in California, it must be licensed as a community pharmacy by the board. If the pharmacy is located outside California and ships drugs to California patients, the pharmacy

must be licensed in the state where it is located and registered as a nonresident pharmacy with the board.

The board has special authority to regulate Internet firms doing business from or shipping drugs to consumers in California. Senate Bill 1828 (Speier, Chapter 681, Statutes of 2000) makes illegal for Internet pharmacies to fill prescriptions without a good faith prior medical examination. There are substantial fines associated with such violations of up to $25,000 per violation. This law responds to one major source of violations of prescription drugs obtained from the Internet where a consumer orders a prescription drug without a valid (or sometimes any) prescription.

In May 2002, the board used this authority to issue an $88.7 million fine to a California pharmacy and two pharmacists who were furnishing drugs via Internet orders that were not legitimate prescriptions. Additional investigations are pending that could result in additional firms being cited and fined.

Also in 2002, the board approved a regulation to allow the board to cite and fine pharmacies for Internet violations without using the Attorney General's Office (as SB 1828 requires in the absence of a board regulation). This regulation is pending review by the Administration at the time this Sunset Report is being written.



PART 2

This section contains the board's responses to specific information requested by the Joint Legislative Sunset Review Committee as specified in Part 2 of their survey

--

Issues Identified and Former Recommendations Made by the Joint Legislative Sunset Review Committee

Blank Intentionally

PART 2

Board's Response to Issues Identified and Former Recommendations made by the Joint Legislative Sunset Review Committee

This section contains the board's response to specific information requested by the Joint Legislative Sunset Review Committee's Sunset Review Survey — specifically Part 2.

There are no specific issues identified by the committee for the 2002 Sunset Review. Listed below are the prior issues of the committee made during the 1996 Sunset Review

Former Issue #1 Should the licensing of pharmacists be continued?

Background
Consumers rely on pharmacists for a broad range of critical services requiring professional judgment and complex, technical skills, which if performed incompetently, could cause patient harm or death. The dispensing and distribution of dangerous drugs and devices by pharmacists must be carefully monitored, controlled, and regulated to minimize problems of abuse, misuse, health care fraud and illegal drug trafficking. Pharmacists are licensed in all 50 states.

Sunset Review Committee Recommendations
The state should continue to license pharmacists.

Actions Taken by the Board of Pharmacy
The board supported this recommendation, as did the Department of Consumer Affairs.

Recommendations for the Future
There is a pharmacist shortage in California as well as nationally. This shortage will become exacerbated in the next few years as the number of prescriptions written is expected to increase to 4 billion by 2004 in response to an aging population, advances in medical treatment that prolong lives and treat serious medical conditions, and new drug products themselves; however, California's and the nation's schools cannot produce enough pharmacists to meet the demand for pharmacists now or expected in the future.

Pharmacists are essential health care practitioners, and pharmacists' care is essential to patients' health. Without a sufficient number of knowledgeable pharmacists, patients will be at greater risk of ineffective drug therapy, medication errors, and medication misadventures. Health costs will increase because of these factors. Patients will also have to wait substantially longer for their prescription medication to be filled unless new dispensing methods are used. The board has identified some steps that can reduce the impact of the pharmacist shortage and over the next year or two will seek to implement these changes.

California also has its own licensing exam, which it gives twice a year. This adds an additional burden to attracting pharmacists into this state. For example, new pharmacy school graduates can take a licensing exam in any other state, any weekday, and become licensed throughout the year. In California, the exam is given in June and January, and release of scores occurs in late August and March, which coincides with peak licensure of pharmacists with the board. But graduates who pass the national exam can begin working as pharmacists in other states weeks before they learn whether they have passed California's exam, which also increases California's difficulty in recruiting pharmacists.

In the future, the board must give its licensure exam more than twice a year, but the current composition of the examination – which contains a short-answer section that must be hand graded – limits the number of exam administrations possible because of the need for hand grading. Moreover, additional resources would be needed to develop, administer and grade more than two exams a year, and the board's ability to obtain additional resources to provide more exams is not likely to occur.

All U.S. schools of pharmacy award the same degree (doctor of pharmacy), and each of these schools has its program accredited by the same agency.

In 2001, the board hired a team of occupational testing experts from four different states to review the national pharmacist examination (North American Pharmacist Licensure Exam or NAPLEX). This team concluded that the NAPLEX meets California's standards for occupational licensing.

As such the board supports the use of NAPLEX, which is a computer adaptive exam, as the test of minimal competency for pharmacists. The board also would develop and administer a California-specific jurisprudence exam that could be administered at computer terminals throughout the country on weekdays. As such, the pharmacists interested in coming to California would not have to wait for one of the two exams each year, but instead could take the exam more locally, without coming to California. California would meanwhile place its testing experts on the national exam committee, and continue to retain and develop its own jurisprudence exam.

Whereas the use of the NAPLEX will not solve the pharmacist shortage, it could substantially reduce the time required for pharmacists in other states to qualify for licensure here. However, use of the NAPLEX is controversial and legislation is required for the transition to this examination. When the board voted in the July 2001 meeting to use the NAPLEX exam, there were two dissenting members. These members indicated that they wanted an exam that measures communication skills.

Former Issue #2 Should the licensing of other classifications regulated by the board be continued?

Background

The Board of Pharmacy licenses a number of facilities and the individuals who work in these facilities. In addition to pharmacists, the individuals licensed by the Pharmacy Board in 1996 were pharmacy technicians, pharmacy interns, and exemptees (non-pharmacists who may oversee certain types of facilities in place of a pharmacist). The board also operates a special evaluation process for foreign-educated pharmacists.

The board issues licenses to the following facilities – pharmacies, nonresident pharmacies, medical device retailers, hypodermic needle and syringe distributors, veterinary food animal drug retailers, out of state distributors, clinics and wholesale drug facilities. All these individuals and facilities are directly involved in the distribution and handling of prescription drugs and devices to patients or practitioners in California.

Sunset Review Committee Recommendations

The Board of Pharmacy should be retained as the state agency to administer pharmacy regulation laws. Regulatory authority of other state agencies over certain licensing classifications should be consolidated under the Board of Pharmacy. The board should also consolidate any overlapping of duplicative licensure requirements for any of its licensing classifications

Action Taken by the Board of Pharmacy

During the 1996 sunset review, the board agreed that medical device retailers, which are non-pharmacy firms that furnish prescription devices to patients, were regulated by a number of other state agencies depending upon the types of products sold by the firms. One area of duplicate requirements concerned those medical device retailers who sold upholstered bedding or wheelchairs, in which case they also had to be licensed by the Department of Consumer Affairs, Bureau of Home Furnishings and Thermal Insulation.

In 1997, the Bureau of Home Furnishings eliminated fees for medical device retailers who were also licensed with the Board of Pharmacy. The board supported this change.

Over the next few years, discussions with the association representing the medical device retailers noted problems with Medi-Cal fraud by some of these firms, provisions that were enforced by the Department of Health Services. Additionally other medical supplies were sometimes prescribed to patients (e.g., adult diapers) and could be paid for by Medi-Cal or other third party payers, yet these firms did not have to be licensed with the Board of Pharmacy nor any other agency. These discussions led to introduction of legislation by the association over several years, one bill of which was ultimately enacted to move the medical device retailer program (and the associated exemptees) to the Department of Health Services in July 2001. The board supported this transfer.

Recommendations for the Future
The board continues to regulate the practice of pharmacy. Recognizing that it is a dynamic field, the board has aggressively sought and supported statutory and regulatory changes to assure that consumer protection is achieved. The board continues to educate its licensees about existing and new requirements. The board continues to take action against licensees who violate pharmacy law, removes unfit pharmacists and unscrupulous pharmacies from practice and tests to ensure that only those with at least minimal competence practice as pharmacists.

All the board's licensing programs have been modified by legislation and/or regulation changes since the 1996 sunset review (see the list of statutory and regulation changes provided in the Introduction Section). Since 1996 the board has added specific sterile compounding licensure requirements for pharmacies, substantially modified requirements for drug wholesalers, and created a retired category of pharmacist license for pharmacists who wish to end their careers as pharmacists without relinquishing their license to the board. Also in July 2002, the board was given jurisdiction over any vendor who sells mercury thermometers since California now requires such vendors to possess a hypodermic needle and syringe permit.

The board will undertake actions in 2002/03 to empower the pharmacist to determine the staffing composition in pharmacies of ancillary staff (i.e., interns, technicians, technician trainees) up to a maximum number, a large change from current requirements that specify ratios of a pharmacist to each type of ancillary staff.

Former Issue #3 Should an independent Board of Pharmacy be continued, or should its operations and functions be assumed by the Department of Consumer Affairs?

Background
The board is an autonomous agency within the Department of Consumer Affairs.

Sunset Review Committee Recommendations
The Board of Pharmacy should be retained as the state agency to administer the pharmacy regulation laws. Legislation should be enacted to continue the board and require a subsequent sunset review in six years.

The board has demonstrated a high degree of innovation and constructive organizational changes to increase productivity and effectiveness. It has one of the better reputations within the Department of Consumer Affairs as a proactive and well-administered regulatory agency. There does not appear to be any compelling reason to believe that there would be cost saving or increased performance were the board to be sunset and its functions assumed by the department.

Action Taken by the Board of Pharmacy
The board supported this recommendation and was pleased with the accolades from the Sunset Review Committee.

Recommendations for the Future
Following sunset review, the board continued to adapt to ever-present change among those the board regulates. In 1997, the board reorganized its activities through adoption of a new strategic plan that implemented its current five-committee structure (Licensing, Enforcement, Communication and Public Education, Legislation and Regulation and Organizational Development). These committees allow a more deliberative process for decision-making than with the whole board meeting approach. The committee structure also provides more opportunities for public comment at the public meetings of the committee, and during board meetings where public comment on committee recommendations is vigorously encouraged. The calendar of meetings held by the board since 1997 illustrates the board's efforts for public and stakeholder input in its decision-making.

Proposing and making regulatory and statutory changes is an essential function of the board, which is necessary for an agency that deals with prescription drugs, automation issues involving patient information or delivery systems for medications, and cost containment to hold down health care expenses. The lists of board-sponsored legislation and regulation changes at the front of this report illustrate the board's activities in this area. Last year, the board sponsored five major bills – each of which was enacted. This illustrates the board's advocacy efforts to further consumer protection and pharmacists' care.

The board has made a significant training effort to educate staff about the need for constant change in operations and the stress issues that arise from having to adapt to ongoing change. Through the committee structure, the board's staff has also been able to provide input early in the process, as has the public during the public meetings on issues before the board.

The board is very proud of its Web site and the two national awards for public education it has received since the last sunset review. The board intends to move forward in this area in the future, despite the recent loss of the two key staff positions responsible for education and communication (via reductions in the 2002/03 state budget that eliminate all vacant positions).

Former Issue #4 Should the composition of the board be changed?

Background
At the time of the 1996 sunset review, the board was comprised of 10 members; seven licensed pharmacists and three public members. The governor appointed the seven licensees and one public member, and the remaining two public members were appointed by each of the two houses of the Legislature.

Sunset Review Committee Recommendation
Add one public member to the board to create an odd number of board members. The Administration should also attempt to assure that all professional members of the board are representative of all aspects of the pharmacy profession.

Board Action Taken
The board supported this recommendation.

One additional public member position was added to the board in January 1998, following enactment of the Senate Business and Professions Committee's bill to implement sunset recommendations. This position is currently vacant – it became vacant June 1 once the "grace year" expired for the prior public board member.

For years, provisions of the Business and Professions Code have specified the composition of certain pharmacist members of the board. The pharmacist composition of the board matches this.

Recommendations for the Future
None. The current size of the board and composition of public and professional members allows all members an opportunity to participate in committee and board activities and discussions.

Former Issue #5 Should the current requirement that inspectors employed by the Board of Pharmacy be licensed pharmacists be eliminated? Should the board's inspectors be granted limited peace officer status as recommended by the Board of Pharmacy?

Background
The Legislative Analyst's Office recommended the elimination of the statutory requirement that its inspectors be licensed pharmacists, and instead allows the use of industry experts (pharmacist consultants) if the need arises for technical expertise. The recommendation was due in part to the board's difficulty in recruiting inspectors who are licensed pharmacists because of the low salary schedules for this classification at the state level.

The Legislative Analyst's Office stated that the board should have the option to hire licensed pharmacist inspectors or other state investigators. Mandating that all inspectors be licensed pharmacists is unique to this board. Other boards do not require that only licensed professionals perform investigation or inspection of suspected violations of their respective licensing acts. Most will use expert professional witnesses as needed.

The Division of Investigation can provide investigators with sworn peace officer status if the need arises.

Sunset Review Committee Recommendation
The requirement that all inspectors for the board be licensed pharmacists should be eliminated. The inspectors should not be granted sworn peace officer status.

Actions Taken by the Board of Pharmacy
Legislation (SB 827, Chapter 759, Statutes of 1997) was enacted which allowed nonpharmacist inspectors to inspect or investigate nonpharmacies or nonpharmacists. The

earlier version of the bill was somewhat broader and closer to what the Legislative Analyst's Office recommended, but opposition from various (non-board) sources opposed those provisions and they were amended into the existing language.

The board's difficulty in recruiting pharmacists as the board discussed in its 1996 Sunset Report, was due to the abysmally low state salary for this classification compared to the private sector. As such, the board was unable to recruit quality pharmacists as inspectors. The inability to offer a competitive pharmacist salary with that offered by the private sector led to significant inspector vacancies during the mid to late 1990s, which created a backlog of complaints and investigations. The board's only other alternative was to hire inadequate pharmacist staff for these important positions, which the board would not do. Meanwhile, the board continued its aggressive efforts to achieve a higher salary for its inspector classification including:

- developing reclassification proposals and salary realignment proposals for the inspector series (denied by the Department of Personnel Administration)
- sponsoring legislation to create statutory links of inspector salaries with the salaries paid to UC pharmacists [SB 2239 (1998), SB 1308 (1999)]; both of which were opposed by the administrations of two governors and were amended out of the bills late in the respective session
- pursuing numerous high-level discussions with administration officials and written requests to the Governor to recognize inspectors as under-compensated workers (denied by Governor Wilson)
- securing continuous application processes to aid in inspector recruitment (which means competitive civil service examinations are given twice a year instead of every two or three years)
- publishing articles about inspector positions available in the board's quarterly newsletter that is mailed to all California licensed pharmacists (for recruitment)
- hiring all inspectors from the private sector at the top step of the inspector salary range (which required specific approval from the Department of Personnel Administration).

Also, the board established specialized complaint handlers to mediate consumer complaints, added administrative staff to review applications for site licenses, and discontinued routine inspections (which are not mandated). Also, pre-license inspections of facilities were discontinued, and a self-assessment process was developed via board regulations so that pharmacies could monitor their own compliance with pharmacy law in the absence of routine inspections.

During the collective bargaining process of 1999, the board's inspectors received a special 10 percent salary adjustment, which coupled with other salary increases provided to all state employees greatly closed the salary differential with the private sector. Additionally, the Department of Consumer Affairs held continuous application processes for the inspector classification – typically two exams a year were conducted – so quality new pharmacists could participate in the interview process and become hired.

By January 2002, the board had filled all 19.5 of its inspector positions, eliminated its backlog of complaints, and reestablished routine inspections of pharmacies. Complaints were being closed within 90 days, and complex investigations involving audits were being closed within 180 days. Additionally consumer satisfaction of board handling of complaints increased with the elimination of the excessive delays. Performance standards for investigations and conducting inspections have aided the board in this substantially improved performance, but this success is also due to efforts by all board staff to respond effectively and efficiently in the public interest.

Other innovations since the last sunset review include: the board became one of the first agencies (if not the first) within the department to pursue use of Penal Code Section 23 to remove dangerous practitioners from practice during which time the board can conduct its investigation to proceed administratively. The board also recently began citing and fining licensees for violations of pharmacy law by using two board members to assess the fines (instead of the executive officer).

Regarding peace officers, in 1998, the board submitted a budget change proposal to allow the use of the Division of Investigation when the board needed peace officers' services. The board uses these services when appropriate. Additionally, one of the board's inspectors became the first nonsworn peace officer drug recognition expert in the country. This is a significant achievement for the individual inspector (who is now a supervising inspector) as well as for the board.

Recommendations for the Future
None.

Former Issue #6 Should the Board of Pharmacy be allowed to hire limited term "in-house" attorneys to prosecute cases on behalf of the board, rather than using the Office of the Attorney General?

Background
In 1996, the committee stated that the board has worked to streamline and speed up its enforcement process. However, it continues to experience significant delays and high costs because of its reliance on the Office of the Attorney General for prosecution of its disciplinary cases. The board recommended that it be allowed to establish a core of attorneys knowledgeable about pharmacy law, and policies pertaining to the board. The board indicated that this arrangement would reduce the time to discipline a licensee and control prosecution costs. The DCA believed that a pilot study could settle the debate regarding the effectiveness of in-house attorneys versus those of the AG's Office.

Sunset Review Committee Recommendation
A pilot project should be established which would allow the Board of Pharmacy, and possibly other boards as determined, to hire limited-term staff attorneys to prosecute disciplinary cases. The department should report to the Legislature comparing the results with those using the current system.

Actions Taken by the Board of Pharmacy
Legislation was introduced in 1997 to implement the changes recommended by the Sunset Review Committee on the Board of Pharmacy. This was one of those provisions introduced. However, this provision was vigorously and immediately opposed by the Attorney General's Office, and the provisions were amended from the bill.

Since then, the board has continued to work with the Attorney General's Office to resolve the cases referred there. Both the board and the Attorney General's Office have strong interests in resolving these cases timely. In the last two years, the board has designated one staff person to perform case management of the cases referred to the Attorney General's Office to help speed their resolution. Both agencies want to reduce the resolution time of these cases, which is too long.

The board has a need for legal services in areas besides those needed to discipline a licensee. The board's regulatory mandate is complex and legalistic. There are federal and state laws regulating the dispensing, distributing and storing of controlled drugs and prescription drugs and devices in California, nationally and even internationally. Sometimes these laws conflict – the more stringent law takes precedence. The area involving patient privacy is very complicated – California's Confidentiality of Medical Information Act provides severe sanctions for those who violate patient privacy. Nationally, the HIPAA requirements, set to go into effect in part in 2003 create other privacy protections and responsibilities. There are a number of state and federal agencies involved in these areas. As such, the board requires a great deal of legal advice to keep up with necessary interpretations of law.

Several years ago, the board sought its own Department of Consumer Affairs legal counsel because of the complexity of the board's legal issues, public records requests and ownership issues arising from applications. (This position would not have been an enforcement litigator – the services targeted in the 1996 sunset report.) This budget change proposal was denied. The board continues to share a portion of one departmental counsel's time, which is also allocated to other boards and programs.

Recommendations for the Future
The board has attempted to obtain its own attorneys for proceeding with enforcement cases under the Administrative Procedure Act, and in a separate route, for obtaining an attorney in the department dedicated solely to work on board issues. Both of these approaches were unsuccessful.

One step the board can pursue is to aggressively manage its cases referred to the Attorney General's Office. And for 2002/03, a strategic goal of the board is to have cases referred to the Attorney General's Office resolved within one year.

Additionally, the board will continue to work with the Attorney General's Office on innovative cases, such as the recent $88 million fine issued by the board to a pharmacy that was selling prescription drugs over the Internet without valid prescriptions.

The board works closely with its liaison counsel from the Attorney General's Office to resolve issues early and receive legal advice in coordinating a statewide enforcement program with diverse staff.

Former Issue #7 Should an electric tracking system be implemented, as recommended by the board, to obtain timely, accurate and complete data for preventing drug diversion of controlled substances?

Background

For years, California has had a "triplicate" prescription system for the prescribing of Schedule II controlled drugs (drugs that have medical uses but that are highly abused). The purpose is to reduce the potential for diversion of these drugs for self-use or street use. The "triplicate" is a specialized prescription form, obtainable from the Bureau of Narcotic Enforcement, in limited numbers to qualified prescribers.

The prescriber prescribes a Schedule II drug using the triplicate form, and keeps one copy. The patient takes the remaining two copies to the pharmacy where the medication is filled. The pharmacy keeps one copy and the original is mailed by the pharmacy to the Department of Justice each month.

The Department of Justice did not have an automated system, and substantially less than 10 percent of the triplicate forms were ever entered into a computer in the mid 1990s. As such, it was extraordinarily difficult to identify abuses in those who were prescribing or dispensing drugs inappropriately. The board believed that this system needed to be automated to capture 100 percent of all Schedule II drugs dispensed by pharmacies within a short period of time after the pharmacy dispensed the drugs or even at the time of dispensing. The process could be implemented in pharmacies almost transparently and at very low cost.

Sunset Review Committee Recommendation

Implement an electronic monitoring system to obtain timely, accurate and complete data for preventing drug diversion of controlled substances as envisioned by the board. However, the board must comply with all mandated requirements to implement any new technology projects.

Actions Taken by the Board of Pharmacy

The board was a vigorous supporter of AB 3042 (Takasugi, Chapter 738, Statutes of 1996) which implemented the Controlled Substances Utilization and Review System (CURES). This bill created a three-year pilot project to evaluate the feasibility of automating the tracking systems for Schedule II drugs. The board contributed $1.05 million from its fund to support the pilot project and another $240,000 for an earlier feasibility study to establish computer parameters for data that would be collected. This funding was secured via statutory provisions.

Complying with all mandated state requirements for new technology projects, the board developed specifications and contracted with two vendors who received and analyzed the data submitted by pharmacies. The board also promulgated regulations mandating the reporting of this data each month by pharmacies. Data collection commenced in May 1998 with pharmacies submitting the data regarding all Schedule II drugs dispensed during a month electronically or on a disk sent to the designated vendor. To speed compliance, the board offered a $75 rebate of licensing fees for any pharmacy that began to submit data within three months.

The board later sponsored legislation to extend the sunset data of CURES for three years (SB 1308, Statutes of 1999), and continue the funding initially authorized in the 1996 legislation (this funding ran out in December 2001, when the Department of Justice assumed the fiscal responsibility).

In 2000, the board convened a high level conference of state and federal authorities and pain management experts to discuss the direction of the prescribing and dispensing of Schedule II substances in California (a report of these proceedings is listed in Part 1 of this report under *List of Reports*). Later this year, the board again sponsored legislation (AB 2018, Thomson) to retain CURES permanently and eliminate the triplicate prescription form, which the board believes has become a deterrent to pain management and relief for patients. However, the Department of Justice opposed the elimination of the triplicate form. In the end, the CURES provisions were deleted from the bill.

In 2002, the board has sponsored legislation to extend CURES five more years (AB 2655). Another provision in this legislation will allow prescribers to request patient profiles of their patients before prescribing any Schedule II drugs – a means to reduce the amount of doctor shopping that occurs by patients seeking to obtain and divert these drugs. Meanwhile during deliberations on the 2002/03 budget, the board along with three other regulatory boards (Medical Board, Dental Board, Osteopathic Board) was designated to fund CURES during the remainder of its limited-term life. The board's share of this funding is $70,000 annually.

The data available from CURES is beneficial to the enforcement efforts of the board and other regulators because it is complete. Data can be sorted based on a number of parameters such as the quantity of a particular drug dispensed, the amount of drugs prescribed for a particular patient or by a particular prescriber, or the amounts of drugs dispensed by a particular pharmacy. The board has used data from CURES for a number of investigations over the years, although the data was not used as the origin for investigations due to the board's inspector vacancies and backlog of complaints.

However later in 2002, the board will begin aggressively investigating pharmacies with high or unusual dispensing characteristics for Schedule II drugs. In June 2002, the board received a freeze exemption to fill an analyst position specifically to perform this function via analysis of CURES data. In years to come, the board believes this will become a source of a number of important investigations.

Recommendations for the Future
The board desires ongoing implementation of CURES and elimination of the triplicate form. In the future, once the electronic prescribing of Schedule II drugs is authorized federally, the triplicate may ultimately be eliminated. However, there is still resistance by law enforcement in California to the elimination of the triplicate form.

Former Issue #8 Should funding be provided, as recommended by the board, to implement a public education program for consumers regarding the importance of talking to pharmacists about their medications, and the role the Board of Pharmacy as a consumer protection agency?

Background
At the time of the 1996 sunset report, the board strongly desired a public education and outreach program, but had no funding for such a program. The board clearly stated its intent to establish a meaningful and visible program to improve the knowledge of the public about the medications they take, the importance of talking to a pharmacist, and the role of the Board of Pharmacy. A budget change proposal the prior year (to start 1996/97) had been denied by the Department of Finance, and a second budget change proposal had been submitted and approved for 1997/98 at reduced levels than initially requested by the board.

Sunset Review Committee Recommendation
Support the Legislature's approval of a budget change proposal submitted by the board to fund and implement a public awareness campaign.

Actions Taken by the Board of Pharmacy
The board has repeatedly made efforts to secure funding for its public education program since the last sunset review. In 1996, the board made its second request in two years via a budget change proposal to establish and maintain an integrated public education program. The board had initially requested funding and one staff person for five years for a total augmentation of $1.3 million. This proposal was denied; however, the board appealed and was able to obtain funding for a two-year program of $263,000 (1997/98) and $304,000 (1998/99). The sunset review committee supported this latter proposal.

The California Board of Pharmacy has twice won national awards for its public education program. In 1999, the board won the *Paul G. Rogers Award* from the National Council for Patient Information and Education for outstanding leadership in the development, production, and dissemination of educational public services. The board's program was noted for its focus to enhance consumers' understanding of the value of high quality communication about medication, and the development and advancement of public policy to support improved medication communication.

In 1997, the board won the *Fred T. Mahaffey Board of the Year Award* of the National Association of Boards of Pharmacy for the state pharmacy board demonstrating outstanding leadership in protecting the public. The focus of this award was the multiple component public education and outreach efforts of the board.

Yet despite these substantial accolades to the success of the board's public outreach program and the documented high economic and health care costs of prescription drug noncompliance to prescribed treatment regimens, the board still had difficulty in obtaining ongoing funding for the public outreach program. The board had to submit three more budget change proposals over the next three years as well as obtain the intervention of the Legislature in 2001 to establish the program permanently with one staff person.

FY 1999/00	Request $312,000 with 1 associate analyst and ongoing funding. *Approved:* $238,000 one-year funding to continue limited program and evaluate effectiveness of program, no staff.
FY 2000/01	Request $500,000 with 1 associate analyst to oversee program and vendor contracts. *Approved:* $238,000 ongoing without staffing
FY 2001/02	Request $87,000 for one associate analyst. *Denied:* Position later inserted into budget by Legislature, and signed by Governor Davis as budget bill.

This position was unfilled when the hiring freeze was implemented in October 2001 (although interviews had just taken place), and was lost in June 2002 when the Legislature abolished all vacant positions. In the future, the board will seek restoration of this position.

The board's public communications and outreach program is divided into components:

- *Health Notes*, which is a compendium of up-to-date treatment methodologies and issues on a specific health care topic, published in a newsletter format for pharmacists and useful to other health care providers as well as to the public.
- brochures and newspaper columns to educate consumers about how to take their medications, the role of the board, how to file a complaint and health columns based on excerpts from *Health Notes* and other consumer brochures and health care issues,
- public forums, where the board works with local activists to arrange health fairs, staffed by pharmacists to respond to patients' inquiries and covered by local media to disseminate the board's message to a wide audience,
- online availability of board publications to the public at the board's website (www.pharmacy.ca.gov).
- Producing four newsletters annually for licensees, advising them of new laws and regulations, board policies, compliance issues, and disciplinary actions taken by the board.

Recommendations of the Board of Pharmacy

The board needs a visible, vital communication and education program. The only way the board can provide optimal consumer protection is to assure patients know the importance of following drug therapy and how to advocate for their own interests and health in dealing

with prescription drugs. Moreover, when there is a problem, consumers need to know that the Board of Pharmacy exists, and how to contact it. By so doing, the board can undertake an investigation when warranted. Education of patients is necessary for the board to fulfill this consumer protection mandate.

This year, even without staff, the board will produce a *Health Notes* on Quality Assurance Programs to aid pharmacists in complying with SB 1339 (Figueroa, Statutes of 2000) to evaluate prescription errors and prevent their reoccurrence. By January 2003, the board will publish another *Health Notes* on Geriatrics.

The board has redesigned and refocused its "Notice to Consumers" which by board regulation, must be posted in every pharmacy or printed on receipts. The new poster will contain an 800 number for consumers to call the board and prominently display the five questions patients should understand before taking prescription medication. The poster will be translated into several other languages in addition to English and Spanish.

Former Issue #9 Should the board be allowed to receive federal FBI fingerprint reports to check on criminal histories of applicants?

Background
The Board of Pharmacy for years has required fingerprint checks of all applicants for licenses and of the owners and officers of facility licenses. These fingerprint checks were performed by the California Department of Justice of all records in their system. However, such checks may not include federal arrest and conviction information or information from other states. Applicants for licensure in California may have criminal backgrounds elsewhere that are not discernable to the board without federal checks. Because the board regulates those who handle, ship and otherwise has legal access to prescription drugs, the board needs a higher level of assurance of the background of its applicants.

Sunset Review Committee Recommendation
The board should be allowed to receive federal FBI fingerprint checks for criminal histories of applicants. However, the board should examine the necessity for all applicants to undergo an FBI check.

Actions Taken by the Board of Pharmacy
In 1997, the Department of Consumer Affairs sponsored a provision to enable a number of agencies in the department to receive FBI fingerprint checks. The board was one of the agencies so authorized.

In mid 2000, the Department of Justice transitioned its fingerprinting processes from one based almost entirely on the submission of fingerprints on cards to electronic submission of prints at terminals throughout California via a process called Live Scan. The Live Scan process was faster than use of fingerprint cards, and applicants could pay the Live Scan operator directly, without having to submit a fingerprint fee to the board, for which the board was billed by the Department of Justice. This faster processing also permitted faster

processing by the FBI, a process used occasionally by the board on an individual basis and which added time to the processing of any application. (Out of state applicants cannot use Live Scan, and still submit their fingerprints on cards.)

In January 2001 with the full implementation of Live Scan throughout the state, the board began requiring federal fingerprint clearances on all new applicants. The board carefully considered the need to seek federal clearances only on some applicants, but was concerned that with the high mobility of the nation's population that arrests elsewhere would not be discerned by the board by other means. The substantially faster processing times for Live Scan would also help assure that applicants did not have to wait months for clearances.

Recommendations for the Future
None.

Former Issue #10 Should the Board of Pharmacy regulate pharmacy management firms?

Background
In 1994 and 1995, the board saw the advent of specialty firms that provided management services to pharmacies. These firms performed payroll operations, ordered and controlled prescription drugs, and performed other management functions. In some cases, this had caused problems, for example these firms can hire pharmacists to work in the pharmacies, but if the pharmacists are impaired or had been disciplined by the board, the board lacked the ability to take action against the management company. The board also did not know who was responsible for these operations; however, they acted very much like licensed pharmacies do with respect to the acquisition and disposition of prescription drugs and pharmacists' care.

Sunset Review Committee Recommendation
There is insufficient information and data needed regarding the extent of the problem created by these management firms to determine whether regulation of these firms is warranted.

Actions Taken by the Board of Pharmacy
The board has encountered similar arrangements since the 1996 sunset review. In 2001, the Department of Health Services advised the board that in hospitals (where the physical hospital premises is licensed by the DHS) pharmacy services must be provided by the Board of Pharmacy-licensed entity, which must match the ownership of the DHS-licensed facility. No subcontracting is allowed.

An emerging problem today arises from the pharmacist shortage and the need for pharmacies to find qualified pharmacists to work, sometimes on a short-term basis. Pharmacies may use the services of relief agencies to find pharmacists under such temporary conditions. But the pharmacists sent by relief agencies to work have in two recent cases have been unlicensed individuals who are not authorized to work as

pharmacies. In such cases the board has no recourse against the relief agency for failing to check the license status of the individuals it sends to work in pharmacies.

Recommendations for the Future
A future newsletter article will focus on this issue to alert pharmacies of the need for them to confirm the licensure status of relief pharmacists. At this time, the board has no other activities planned for this issue.

Former Issue #11 Should-non-licensed pharmacy owners be required to take and pass a written examination prior to licensure as recommended by the board?

Background
California allows anyone other than a prescriber to own a pharmacy. Certain other states require that only a pharmacist can own a pharmacy. The board expressed concern that non-licensed owners may not be as knowledgeable about pharmacy law including knowledge of federal and state laws regarding the control, tracking and dispensing of controlled substances as pharmacists. As such, the board proposed that passing a law exam be required as a condition of licensure for any non-licensed pharmacy owner.

Sunset Review Committee Recommendation
The board's recommendation to require a written examination for non-licensed pharmacy owners is not justified given the information provided by the board to the committee. Moreover, current law requires that there be a "pharmacist-in-charge" at every pharmacy. The PIC is knowledgeable and responsible for the operations of the pharmacy.

Actions Taken by the Board of Pharmacy
None. The board agreed that there was no evidence that a law exam would add to improved consumer protection from non-licensed pharmacy owners.

Recommendations for the Future
None.

Former Issue #12 Should an examination be required, as recommended by the Board of Pharmacy, before a pharmacy technician can be registered by the board?

Background
The board has licensed pharmacy technicians since 1992 to assist pharmacists in performing nondiscretionary tasks under the supervision of a pharmacist. At the time the board's requirements were enacted (by statute) and promulgated (by regulation), there was no examination available to test the knowledge of pharmacy technicians. Instead, applicants qualify for licensure by either experience or by education.

Sunset Review Committee Recommendation
The board did not provide sufficient justification to require a written examination for pharmacy technicians.

Actions Taken by the Board
A pharmacy technician examination was developed nationally in 1995. However, passing this examination is not an approved route of qualification to becoming a pharmacy technician currently in California.

In 2001, the board commissioned a Pharmacy Manpower Task Force to evaluate options for assuring ongoing patient care by pharmacists given a current and future pharmacist shortage. Several of the recommendations involve pharmacy technicians:

- Allow individuals who have passed the national Pharmacy Technician Certification Board Exam to become registered as technicians in California.
- Require all pharmacy technicians to become certified by the Pharmacy Technician Certification Board as the sole qualifying method to becoming licensed or after a specific date, renewing pharmacy technician licenses.
- Increasing the ratio and role of pharmacy technicians could mitigate the pharmacist shortage if appropriate quality assurance is in place to assure the pharmacist's role in performing patient care services.
- The task force believed that if additional or higher-level duties are permitted to pharmacy technicians, the technicians need to possess a higher level of knowledge. Passing the national pharmacy technician certification examination would be such a measure.

Recommendations for the Future
The board has approved proceeding with a statutory change to authorize the Pharmacy Technician Certification Board Exam (PTCB exam) as a qualifying method to becoming a pharmacy technician.

The board has also added to its strategic plan evaluation of the feasibility of using the PTCB exam as the sole qualifying method for becoming or maintaining licensure as a pharmacy technician.